National Diabetes & Digestive & Kidney Diseases
Advisory Council Orientation Handbook

FEBRUARY 2013

National Institute of
Diabetes and Digestive
and Kidney Diseases

Orientation for New Advisory Council Members

A MESSAGE FROM THE DIRECTOR, NIDDK

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is one of 27 Institutes and Centers that make up the National Institutes of Health (NIH), part of the Public Health Service in the U.S. Department of Health and Human Services. The Institute conducts and supports basic and clinical research in some of the most serious, common, disabling, and costly conditions affecting the public's health. The diseases in NIDDK's research mission cut across the full spectrum of medicine and include:

- Diabetes and other endocrine diseases;
- Cystic fibrosis and other inherited diseases;
- Digestive diseases;
- Obesity;
- Nutrition;
- Diseases of the kidney, genitourinary tract, and blood.

Most arise from the complex interaction of genetic, autoimmune, neuroendocrine, metabolic, nutritional, and environmental factors. Some diseases such as diabetes, obesity, hepatitis, and kidney failure disproportionately affect minority populations. NIDDK funds research projects that relate directly to these diseases, but it also places a high priority on fundamental, untargeted research.

Training is critically important to continued progress in medical research. NIDDK supports research training and career development, with special emphasis on increasing the ranks of physician scientists and recruiting underrepresented minorities and women into biomedical research careers.

The National Diabetes and Digestive and Kidney Diseases Advisory Council's most important purpose is to make recommendations regarding the funding of grant applications, focusing primarily on the relevance to the programmatic missions and priorities of the Institute. The Council also has the responsibility to ensure the adequacy of the scientific review by the initial review groups. In addition, the Council offers advice on a wide variety of policies and programs within the Institute.

As you begin service on the National Diabetes and Digestive and Kidney Diseases Advisory Council, we hope this orientation material will help answer some of your questions and provide the information you will need in your role as a Council member. In addition, your comments on the usefulness of this material and suggestions for improvement will be appreciated.

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National Institute of Diabetes
and Digestive
and Kidney Diseases
National Institutes of Health

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NIH Gateway Center Map

Main Visitor Entrance: NIH Gateway Drive

Gateway Center - Building 66 (for pedestrians entering campus)

- Open Monday – Friday 6am – 10pm
- Closed on Weekends and Observed Holidays
- After 10pm weekdays, all day weekends and holidays, pedestrian visitors enter via Commercial Vehicle Inspection Facility (CVIF) – Building 67 (on Rockville Pike between North Drive and Wilson Drive)

Gateway Inspection Station - Building 66A (for vehicles entering campus)

- Monday-Friday: 5am – 10pm
  Weekends and after 10 pm: Closed
  After 10pm on weekdays, all day weekends, and holidays, visitors in vehicles should enter campus via the CVIF
- All vehicles and their contents will be inspected upon entering the campus.
- After inspection, vehicles enter campus at Center Drive
- Roadway at Center Drive is for entering campus only; visitors exiting campus may exit from other open locations.

Multi-Level Parking Garage 11 – MLP-11 (car inspection not required; visitor badges obtained at Gateway Visitor Center – Bldg 66) Hours: Monday - Friday: 6am – 9pm (entrance) 6am – 11pm (exit) Cost: $2 per hour for the first three hours, $12 maximum for entire day. Closed weekends.

Security Procedures for Entering the NIH Campus:

All visitors and patients – **please be aware**: Federal law prohibits the following items on Federal property: firearms, explosives, archery equipment, dangerous weapons, knives with blades over 2 ½ inches, alcoholic beverages and open containers of alcohol.

The NIH has implemented security measures to help ensure the safety of our patients, employees, guests and facilities. All visitors must enter through the **new** NIH Gateway Center and Visitor Center on Rockville Pike just south of the Metro station and previous visitor entrance at South Drive and Rockville Pike. **Except for persons parking in multi-level parking garage at the NIH Gateway Center (MLP-11)**, all vehicles entering the campus must submit to a vehicle inspection.

Whether arriving by Metro, hotel shuttle, or private or commercial vehicle, visitors over 15 years of age must show one (1) form of a government-issued photo ID—driver's license, passport, green card, etc**.** Visitors under 16 years of age must be accompanied by an adult.

Tobacco-Free Campus – Effective October 1, 2008, the use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings; on all outside property or grounds, including parking areas; and in government vehicles.

Vehicle Inspections – Except for those parked in MLP-11, all vehicles and their contents will be inspected upon entering the campus. Additionally, all vehicles entering certain parking areas will be inspected, regardless of any prior inspection. Drivers will be required to present their driver's license and may be asked to open the trunk and hood. If you are physically unable to perform this function, please inform the inspector and they will assist you.

Vehicle inspection may consist of any combination of the following: Detection Dogs Teams (K-9), Electronic Detection Devices and Manual Inspection.

After inspection, you will be issued a vehicle inspection pass. It must be displayed on your vehicle's dashboard while you are on campus. The inspection pass is not a "parking permit." It only grants your vehicle access to enter the campus. You can only park in designated parking areas.

Personal Inspections – All visitors should be prepared to submit to a personal inspection prior to entering the campus. These inspections may be conducted with a handheld monitoring device, a metal detector and by visible inspection. Additionally, your personal belongings may be inspected and passed through an x-ray machine.

If driving onto campus, the personal inspection and issuance of a visitor badge will take place where your private or commercial vehicle (including a taxi) is inspected.

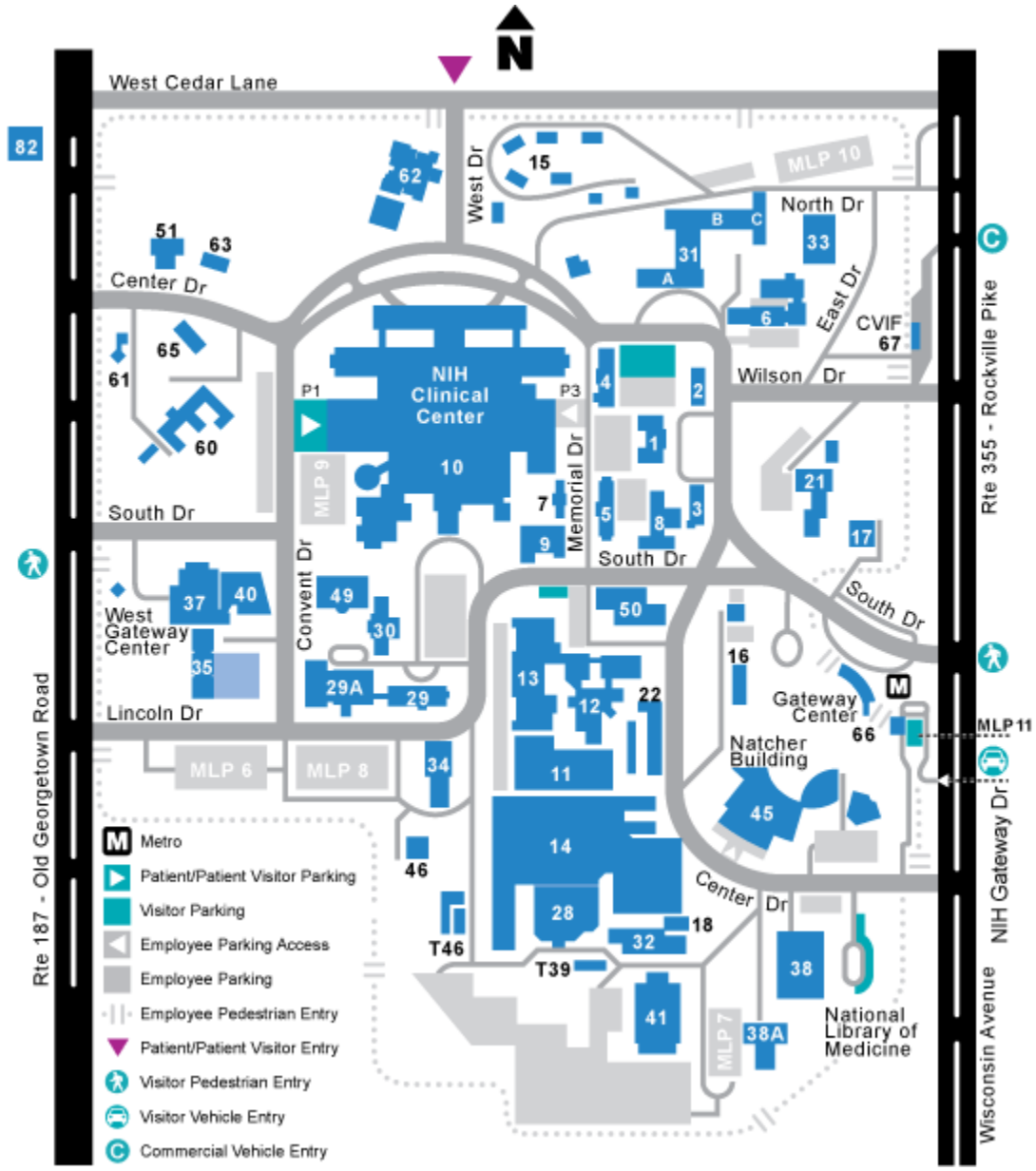
If you parked in the NIH Gateway Center multi-level garage (MPL-11), the personal inspection and issuance of a visitor badge will take place in the Visitor's Center. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://dtts.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp. Directional signs within Building 31 will guide you to the meeting room.

Visitor passes must be prominently displayed at all times while on the NIH campus.

To learn more about visitor and security issues at the NIH, visit: http://www.nih.gov/about/visitor/index.htm.

For questions about campus access, please contact the ORS Information Line at orsinfo@mail.nih.gov or 301-594-6677, TTY - 301-435-1908.

NIH Visitors Map of Campus



Street Address:
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

See Parking on Following Page

General Visitor Parking Information

Parking:

Visitors may park at the **Gateway Parking Garage (MLP-11)** (see Gateway Center Map) or in designated visitor parking lots (see Campus Map):

Monday – Friday, 6am – 9pm (entrance); 6am – 11pm (exit):
$2.00 per hour for the first three hours
$12.00 for the entire day

Metered parking lots:
Monday – Friday, 7am – 7pm
$2 per hour

Arriving at NIH:

When traveling to the main NIH campus, use of the Metro is strongly encouraged. Visitor parking lots on the NIH campus fill up quickly.

The NIH Has implemented security measures to help ensure the safety of our patients, employees, guests, and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gateway Visitor Center. You will be asked to submit to a vehicle and personal inspection.

Visitors over 15 years of age must provide a form of government-issued ID such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult.

If traveling via Metro or hotel shuttle to Medical Center Metro stop: The Washington D.C. Metro-Rail system Red Line has a station right on the NIH campus, called "Medical Center." Once you're out of the station, it's a short walk to the NIH Visitor Center where you will go through the NIH security procedures and receive a visitor's badge. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://dtts.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp. Directional signs within Building 31 will guide you to the meeting room

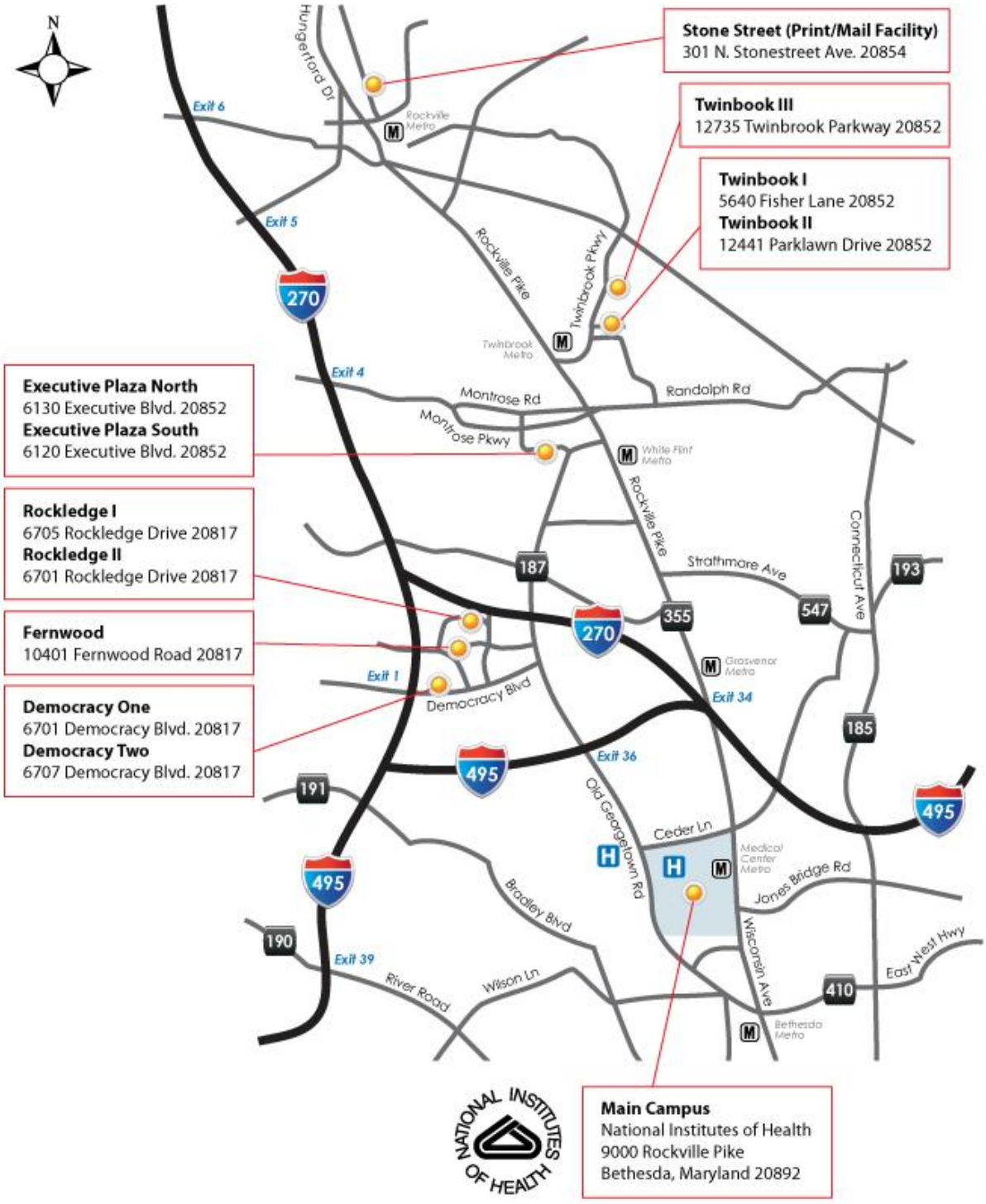
If taking a taxi directly to the meeting site: Upon entering the campus please let the driver know that you wish to be dropped off in front of Building 31. **The taxi must first go through an NIH security inspection of the car, and you and the driver must go through the security procedures and receive visitor badges**. Directional signs within Building 31 will guide you to the meeting room.

If driving private vehicle to the meeting site: Unless you choose to park in the NIH Gateway Center parking garage, receive your security processing at the Visitor Center, and take a shuttle to Building 31, you and your car must first go through security procedures. Visitor parking is located directly across from Building 31 (see **circles** on map). Parking fees are $12 per day and are fully reimbursable. Directional signs within Building 31 will guide you to the meeting room.

Vehicle and Visitor passes must be prominently displayed at all times while on the NIH campus.

No Smoking
No Eating or Drinking
No Animals (except service animals)
No Audio (without earphones)
No Litter or Spitting
No Dangerous or Flammable Items

Bethesda Area Map Showing NIH Campus and Off-Campus Facilities



Glossary of Terms

For extensive list of grant terms see http://grants.nih.gov/grants/glossary.htm

A

Accession Number – Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Acquisition – Obtaining supplies or services by the Federal Government with appropriated funds through purchase or lease.

Active Grant – A grant meeting the following criteria: (1) Today's date is between the budget start and end dates; (2) The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Activity Code – A three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). *See* Funding Mechanisms in NIDDK section of Background Information.

Administrative Expenses – Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Administrative I/C – The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.

Administrative Supplement – Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Amendment (amended or revised applications) – Resubmission of an unfunded application revised in response to a prior review.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application – A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Identification Numbers – The application number identifies: type of application (1); activity code (R01); organization to which it is assigned (DK); serial number assigned by the Center for Scientific Review (CSR) (183723); suffix showing the support year for the grant (-01); other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. *See* Sample Application Number Graphical Overview of Grants Process.

Application Types – Type 1, New; Type 2, Competing continuation (a.k.a. renewal, re-competing); Type 3, Application for additional (supplemental) support; Type 4, Competing extension for an R37 award or first non-competing year of a Fast Track SBIR/STTR award; Type 5, Non-competing continuation; Type 7. Change of grantee institution; Type 9, Change of NIH awarding Institute or Division (competing continuation.

Appropriation – Law authorizing Federal Agencies to obligate funds and make payments from the U.S. Treasury for specified purposes. Appropriations are in annual acts and permanent law.

Approved Budget – The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.

Award – The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Awarding Office – The NIH I/C responsible for the award, administration, and monitoring of particular grants.

B

Bilateral Agreement – A general science agreement between the U.S. and a foreign country. Grant applications from institutions in these countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Bridge Awards (R56) – Provides limited interim research support based on the merit of a pending R01 application while current researcher or new applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R56 with 1 year of funding, which the PI can choose to spend over a 2-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R56 mechanism. Interim funding ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Budget Appropriation – The yearly amount given to a Government Agency by Congress.

Budget Period – The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

C

Career Development Awards (CDA K Series) – Award supporting Ph.D.s and clinicians who wish to develop a career in biomedical research.

Capital Expenditure – The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds.

Clinical Research – Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual.

Clinical Trial – A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects); Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety; Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use; Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Close Out – Procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy; includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

Co-Funding – Funding arrangement through which two or more Institutes or Centers pay for a grant.

Co-Investigator – An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS). Note: NIH does not recognize the term "co-PI."

Commitment Base – Funds used for non-competing (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Competing Applications – Either new or re-competing applications that must undergo initial peer review.

Competing Continuation – Application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)

Competitive Range – Contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.

Concept – The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts are brought before the Advisory Council for

concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Conflict of Interest – Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement – Formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Constant Dollars – Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Contract (R&D) – Award instrument establishing a binding legal procurement relationship between NIH and a recipient obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute to pay for it.

Contracting Officer – Government employee authorized to execute contractual agreements on behalf of the Government.

Cooperative Agreement (U Series) – Support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Council/Board, Advisory – National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round – At NIH, there are typically three council rounds each fiscal year: September. January/February, and May/June. Application receipt dates, initial review dates, and council review dates all fall within one of these council rounds. Incoming grant applications all are assigned to a council round.

Critique – An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at a meeting.

Current Dollars – Actual dollars awarded, without adjustment for inflation.

D

Direct Costs – Costs that can be specifically identified with a particular project or activity.

Direct Operations – Funds for salary and other administrative costs.

Dual Assignments – Applications simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System – Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

DUNS Number – The Data Universal Numbering System (DUNS) number is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is recognized as the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in Commons.

E

Early Stage Investigator (ESI) – A New Investigator (*see* definition under N) who is within 10 years of completing a terminal research degree or within 10 years of completing medical residency. Between 1980 and 2001, the duration of postdoctoral training increased and the average age at which an investigator first obtained R01 funding increased by more than 5 years. Under the ESI program (NOT-OD-08-121 released September 26, 2008), New Investigators identified as ESIs will have their career stage considered at the time of review and award of R01 applications. By providing this advantage to ESIs, NIH can directly encourage earlier application for NIH research grant support. In some cases there may have been one or more lapses in the period of research or research training after the terminal degree or completion of medical residency. A new NIH Guide Notice (NOT-OD-09-034, released December 31, 2008, by the Office of Intramural Research) describes the procedures for requesting an extension of the ESI period and the conditions under which such extensions can be considered.

Electronic Research Administration (eRA) – NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required.

Enrollment Data – Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment – An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.

eRA Commons – A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required. At this site applicants access the status of their applications and grantees access the status of their awards, submit reports, and make requests electronically

Expiration Date – The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Research – Research supported by NIH to researchers and organizations outside the NIH through a grant, contract, or cooperative agreement.

F

Facilities and Administrative Costs (F&A) – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

Federal Acquisition Regulations (FAR) – Laws regulating government contracting.

Federal Advisory Committee Act (FACA) – A law regulating Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Register – An official, daily publication communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance.

Federal-Wide Assurance (FWA) – Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections—HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.

Fee – An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as "profit."

Fellowship - An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.

Fiscal Year (FY) – The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2009 – Started October 1, 2008 and ends September 30, 2009.

Full-Time Appointment – Number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Funding Opportunity Announcement (FOA) – *See* Initiative.

G

Gender – Human subject term indicating a classification of research subjects into women and men.

Grant – Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals – A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Project Period – Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 2008 can be divided into competitive segments 2008 to 2012, 2012 to 2016, etc.

Grant Start Date – Official date a grant award begins; same as the first day of the first budget period.

Grantee – Organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Officer (GMO) – An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.

Grants Management Specialist (GMS) – An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

Grants.gov – An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (DHHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to http://www.grants.gov/.

H

High Risk/High Impact (HR/HI) – A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

Human Subjects Assurance – A document filed by an institution conducting research on human subjects with the Office for Human Research Protections—HHS that formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

I

Identifier – Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "Facility and Administrative Costs."

Information for Management, Planning, Analysis, and Coordination (IMPAC) – A computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

Informed Consent – Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Initial Peer Review Criteria – *Significance:* Is the topic important? Will it advance Scientific Knowledge? ***Approach:*** Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? ***Innovation:*** Does the proposal involve new ideas or methods; does it challenge existing paradigms? ***Investigator:*** Does the investigator and collaborators have the training and experience to do the work? ***Environment:*** Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations? Note: criteria-based scoring commences in 2009.

Initiative – A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not. *See* Funding Opportunity Announcement (FOA)

Institutional Base Salary – The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Institutional Review Board (IRB) – IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Interactive Research Project Grant (IRPG) – An award made to two or more investigators funded independently as R01 grantees but brought together as a collaborative group receiving additional support for collaborative work, shared resources, or the exchange of ideas.

Interagency Agreement – Formal agreement among Government agencies to collaborate on and fund research; Y series activity code.

Integrated Review Group (IRG) – A cluster of study sections responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.

Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SROs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO or GTA.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Investigational New Drug (IND) – Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research – Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research.

J

Just-In-Time – Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

K

Key Personnel – The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.

M

Matching or Cost Sharing – The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Mechanism – Another term for Activity Code.

MEDLINE - National Library of Medicine's database for scientific publications.

Minority Group – Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.

Model Organism – Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Modular Application – A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Monitoring – A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Multiple Principle Investigator – Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution.

N

New Application (award, grant) – Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.

New Investigator – New investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: Pathway to Independence Award-Research Phase (R00); Small Grant (R03); Academic Research Enhancement Award (R15); Exploratory/Developmental Grant (R21); Clinical Trial Planning Grant (R34); Dissertation Award (R36); Small Business Technology Transfer Grant-Phase I (R41); Small Business Innovation Research Grant-Phase I (R43); Shannon Award (R55); NIH High Priority, Short-Term Project Award (R56). Additionally, an individual is not excluded from consideration as a "New Investigator" if he/she has received an award from the following classes of awards: Training-Related and Mentored Career Awards; Fellowships (F05, F30, F31, F32, F34, F37, F38); Mentored-career awards (K01, K08, K22, K23, K25, K99-R00; Other mentored career awards (developmental K02 as used by NINDS and the developmental K07); Loan repayment contracts (L30, L32, L40, L50, L60). Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. *See* Early Stage Investigator.

Non-Competing Continuation – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.

Non-Competing Grant – An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Notice of Award (NoA) – The legally binding document notifying the grantee and others that an award has been made. The NoA contains or references all terms and conditions of the award documenting the obligation of Federal funds and may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA).

Not Recommended for Further Consideration (NRFC) – A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review. The study section does not recommend funding; the application cannot be funded by an Institute.

O

Obligation – Data based on NIH funds that have been awarded by an NIH Institute/Center.

Office of Extramural Research (OER) – NIH office overseeing policies and guidelines for extramural research grants.

Office for Human Research Protections (OHRP) – HHS office overseeing human subject protection for HHS-supported research.

Office of Laboratory Animal Welfare (OLAW) – NIH office overseeing compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Office of Management and Budget (OMB) – Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants.

On Time – Paper applications using "standard" submission dates are on time if postmarked on or before the submission date. Electronic applications are on time if successfully submitted to Grants.gov by 5 p.m. local time on the date indicated. Note: For both paper and electronic submissions, when these dates fall on a weekend or holiday, they are extended to the next business day.

Organization – A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Organizational Code – A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. NIDDK's organizational code is DK.

Other Research Grants – Research grants not classified as research projects or research centers.

Other Support – Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

Overlap of Support – Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

P

Program Announcement Reviewed in an Institute (PAR) – Program Announcement with special receipt, referral and/or review considerations.

Parent Announcement – NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism [e.g., Research Project Grant (Parent R01)].

Payback – Time and effort fellows and T32 trainees must repay the Government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline – A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Peer Review – A system for evaluating research applications using reviewers who are the professional equals of the applicant.

Percentile – Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.

Person Months – Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Pre-application – A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

President's Budget – The annual budget request submitted to Congress by the U.S. President. The process begins with a budget request from the IC, which, as part of the entire NIH budget request, is modified by the Office of Management and Budget.

Principal Investigator – An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.

Prior Approval – Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds.

Priority score – A numerical rating that reflects the scientific merit of the proposed research relative to stated evaluation criteria.

Privacy Act – A law protecting against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs carrying out their missions through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA) – An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts.

Program Balance – The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Classification Code (PCC) – An internal code unique for each I/C indicating the I/C's scientific interest and used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

Program Official (PO) – The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

Programmatic Reduction – The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Number – Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Project Period – The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

Protocol – Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

Public Access Policy – The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states: *The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication:* Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

PubMed – Provides access to citations from biomedical literature. It includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources. These citations are indexed with a PMID, a series of numbers.

R

Rating Criteria – *See* Initial Peer Review Criteria.

Real Property – Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Rebuttal – Procedure for contesting the peer review of a grant application. Synonymous with appeal.

Receipt, Referral, and Assignment of Applications – Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self assign.

Recipient – Organizational entity or individual receiving a grant or cooperative agreement. *See* Grantee.

Recommended – Designation given by a study section advising funding of an application. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support – Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Re-Competing – Grant whose term (e.g., 4 years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.

Request for Application (RFA) – The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (RFP) – Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Research – A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed "research and development."

Research Grants – Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs. Includes the following: R,P,M,S,K,U series (excluding UC6) DP1, DP2, D42, G12.

Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Portfolio – The cohort of grants supported by a given NIH organization.

Research Projects – Includes the following selected Research Grant and Cooperative Agreement activities: R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Project Grant (RPG) – Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. *See* Research Projects.

Research Supplement – Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Restriction – Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.

Resubmission – Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term was "revision." A resubmission has an entry in its application identification number (e.g., A1).

Review Cycle – Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review.

Revision – Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now “resubmission” in Grants.gov.

S

Salary Cap/Limitation – A legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

Scientific Overlap – Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Scientific Review Officer (SRO) – Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Scientific Review Group (SRG) – The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. Also known as Study Section.

Scored – In the peer review process, applications judged by a study section to be competitive (i.e., generally in the upper half of the applications reviewed). These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Selective Pay – The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Set-Aside – Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Signing Official (SO) – Person with has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Small Business Concern – A business independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

Small Business Innovation Research (SBIR) – A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs.

Small Business Technology Transfer (STTR) – A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs.

Special Emphasis – The NIDDK's policy to set aside funds that are used by the respective program divisions to fund meritorious grants whose competitive position places them beyond the established regular payline. It is the responsibility of the respective program divisions to identify such grants and through its established review procedures to determine which grants meet the Special Emphasis (SE) criteria and receive Subcouncil endorsement for funding. Each such application is then nominated for the Division Director's concurrence and approval by the Institute Director.

Specific Aims – A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).

Statement of Work (SOW) – In a contract proposal, the detailed description of the work to be performed under the contract.

Streamlined Non-Competing Award Process (SNAP) – Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP.

Streamlined Review (formerly Triage) – In the CSR peer review process, applications judged by a study section to be in the lower half of the applications evaluated in a given review round. These applications are generally not discussed during the study section meeting, but returned to the applicant with the assigned reviewers' written comments with no priority score. *See* Unscored.

Study Section – Panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called scientific review group (SRG) or initial review group (IRG).

Subaward – Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.

Success Rate – Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers. NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.

Success Rate Base – The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Summary Statement – A combination of the reviewers' written comments and the Scientific Review Administrator's (SRA's) summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Supplement – A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3 application or award, a supplement can be either non-competing (administrative) or competing (subject to peer review).

T

Targeted Research – Research funded as a result of an Institute set-aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research.

Technology Transfer – Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local governments.

Terms and Conditions of Award – All legal requirements imposed on a grant by NIH, whether based on statue, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Tethered Application/Grant – When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the collaborative project. All applications are linked by a common project title and by cross-references within each application.

Total Project Costs – The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Training Awards – Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Translational Research – Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Triage – *See* Streamlined Review

Type – *See* Application Types.

U

Underrepresented Group – Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs.

Unscored – In the Center for Scientific Review peer review process, applications judged by a study section to be noncompetitive are generally in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed and applicants receive a summary statement. Between FY 1992 and FY 1995 the term "Not Recommended for Further Consideration" (NRFC) referred to noncompetitive applications.

V

Validation – The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

W

Withholding of Support – A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Book of NIH Abbreviations and Acronyms

Letter Codes Designating Funding for NIH Institutes, Centers in Grant Applications

Abbreviation	NIH Institutes, Centers	Letter Code Designating Funding Institute In Grant Applications
CC	Clinical Center*****	
CIT	Center for Information Technology*	
CSR	Center for Scientific Review*	
FIC	John E. Fogarty International Center	**TW**
NCATS	National Center for Advancing Translational Sciences	**TR**
NCCAM	National Center for Complementary and Alternative Medicine	**AT**
NCI	National Cancer Institute	**CA**
NEI	National Eye Institute	**EY**
NHGRI	National Human Genome Research Institute	**HG**
NHLBI	National Heart, Lung, and Blood Institute	**HL**
NIA	National Institute on Aging	**AG**
NIAAA	National Institute on Alcohol Abuse and Alcoholism	**AA**
NIAID	National Institute of Allergy and Infectious Diseases	**AI**
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	**AR**
NIBIB	National Institute of Biomedical Imaging and Bioengineering	**EB**

*** Does Not Make Extramural Awards**

Abbreviation	NIH Institutes, Centers, Offices	Letter Code Designating Funding Institute In Grant Applications
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	**HD**
NIDA	National Institute on Drug Abuse	**DA**
NIDCD	National Institute on Deafness and Other Communication Disorders	**DC**
NIDCR	National Institute of Dental and Craniofacial Research	**DE**
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	**DK**
NIEHS	National Institute of Environmental Health Sciences	**ES**
NIGMS	National Institute of General Medical Sciences	**GM**
NIH	National Institutes of Health	
NIMH	National Institute of Mental Health	**MH**
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)	**MD**
NINDS	National Institute of Neurological Disorders and Stroke	**NS**
NINR	National Institute of Nursing Research	**NR**
NLM	National Library of Medicine	**LM**
OD	Office of the Director	**OD**

Acronym	Definition
A	
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AAPHP	American Academy of Pediatrics
ABL	Applied BioScience Laboratories for Acquired Immunodeficiency Syndrome
ABRCMS	Annual Biomedical Research Conference for Minority Students
ABSL	American Bio-Safety Level
ACD	Advisory Committee to the Director
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families (DHHS)
ACGME	Accreditation Council for Graduate Medical Education
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society
ACS	American College of Surgeons
ACSI	American Customer Satisfaction Index
ACSR	AIDS and Cancer Specimen Resource, NCI
ACTG	AIDS Clinical Trials Group
ACTIS	AIDS Clinical Trials Information Service
ACTU	AIDS Clinical Trials Unit
ACUC	Animal Care and Use Committee
ADAMHA	Alcohol Drug Abuse and Mental Health Administration (now **SAMSHA**)

ADB	Automated Data Base System
ADB	Administrative Database System (NIH)
ADC	AIDS Dementia Complex
ADCR	Associate Director for Clinical Research
ADD	Attention Deficit Disorder
AdEERS	Adverse Event Expedited Reporting System
ADP	Automated Data Processing
ADR	Adverse Drug Reactions
ADR	Alternative Dispute Resolution
AE	Adverse Event
AER	Adverse Event Reporting
AFGE	American Federation of Government Employees
AFIP	Armed Forces Institute of Pathology
AFIP	Animal Facilities Improvement Program
AFL/CIO	American Federation of Labor/Congress of Industrial Organizations
AGEMAP	Atlas of Gene Expressions in Mouse Aging Project
AGRICOLA	AGRICultural OnLine Access
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AI	Amelogenesis Imperfecta
AI/ANO	American Indian/Alaskan Native Organization
AID	U.S. Agency for International Development
AIDS	Acquired Immunodeficiency Syndrome
AIDSinfo	HHS AIDS information Web site
AIEDRP	Acute Infection and Early Disease Research Program

AIRO	Agency Intramural Research Integrity Officer
AIRO	American Indian Research Opportunities
AITRC	Allergy, Immunology, and Transplantation Research Committee
AITRP	AIDS International Training and Research Program, FIC
AJCC	American Joint Committee on Cancer
AL	Annual Leave
ALAT	Assistant Laboratory Animal Technician (Certified by AALAS)
ALERT system	HHS system for disseminating information to Public Health Service officials about organizations or people charged with or found to have engaged in scientific misconduct (PHS)
AMA	American Medical Association
AMB	AIDS Malignancy Bank
AMC	AIDS Malignancy Consortium
AMC	Acquisition Management Committee
AMD	Age-related Macular Degeneration
AMHPS	Association of Minority Health Professionals Schools
AMIA	American Medical Informatics Association
AMLCD	Active matrix liquid crystal display
AMSSC	Administrative Management Systems Steering Committee
AMWG	AIDS Malignancies Work Group
ANL	Argonne National Laboratory, Argonne, IL
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AO	Administrative Official/ Administrative Office/ Administrative Officer
AOA	Administration on Aging
AP	Acquisition Plan
APA	Administrative Program Assistant

APAC	Annual Payback Activities Certification
APAO	Asian and Pacific Islander American Organization
APC	NIH Purchase Card Program Agency Program Coordinator
APD	Animal Program Director
APHA	American Public Health Association
APHIS	USDA - Animal and Plant Health Inspection Service
API	Application Programming Interfaces
APN	Advanced Practice Nursing
ARA	Awaiting Receipt of Application
ARAC	Administrative Restructuring Advisory Committee/Work Group on Acquisition
ARAC	AIDS Research Advisory Committee (NIAID)
ARB	Architecture Review Board
ARC	Administrative Resource Center
AREA	NIH Academic Research Enhancement Award (R15)
ARL	U.S. Army Research Laboratory
ARND	Alcohol-related Neurodevelopmental Disorder
ARRA	American Recovery and Reinvestment Act of 2009
ARRR	AIDS-Related Research Review
ARS	Agriculture Research Service
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	As Soon As Possible
ASB	Administrative Services Branch
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASDC	Administrative Skills Development Curriculum

ASH	Assistant Secretary for Health, PHS
ASI	Addiction Severity Index
ASP	Animal Study Proposal
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPER	Assistant Secretary for Personnel Administration, DHHS
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
AT	Administrative Technician
ATCC	American Type Culture Collection, Manassas, VA
ATI	Analytic Treatment Interruption
ATIS	AIDS Treatment Information Service
ATPM	Association of Teachers and Preventive Medicine
ATSDR	Agency for Toxic Substances and Disease Registry
AVEG	AIDS Vaccine Evaluation Group
AVEU	AIDS Vaccine Evaluation Unit
AVRC	AIDS Vaccine Research Committee
AWA	Animal Welfare Act
AWOL	Absence Without Official Leave
AWS	AIDS-associated Wasting Syndrome
AZT	Zidovudine (generic name) or Azidothymidine

B

B&F	Buildings and Facilities
B&P	Bid and Proposal
B/Start	Behavioral Science Track Award for Rapid Transition

BAA	Broad Agency Announcement
BAFO	Best and Final Offer
BARC	Beltsville Agricultural Research Center
BBBP	Biobehavioral and Behavioral Processes
BC	Biomarker Consortium
BC/BS	Blue Cross/Blue Shield
BCP	Best Community Practice and Biophysical and Chemical Sciences
BCS	Biochemical Sciences
BDCN	Brain Disorders and Clinical Neuroscience
BDP	Biopharmaceutical Development Program
BDR	Budget Data Request
BEA	Bureau of Economic Analysis
BECON	Bioengineering Consortium (NIH OD)
BEMIS	Biomaterials and Medical Implant Science
BEP	Bureau of Engraving and Printing
BESA	Border Epidemiologic Study of Aging
BEST	Biomonitoring of Environmental Status and Trends
BFRL	Building and Fire Research Laboratory
BGCRG	Breast and Gynecologic Cancer Research Group
BHPr	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BIC	Business Information Center
BIG	Blacks in government
BIGR	Biomaterials and Information for Genomic Research™ (Ardais Corporation)
BIMAS	Bioinformatics Molecular Analysis Section

BIO	Biotechnology Industry Organization
BIRADS	Breast Imaging Reporting and Data System
BIRN	Biomedical Informatics Research Network
BIS	Bureau of Industry and Security
BISM	Blind Industries and Services of Maryland
BISTI	Biomedical Information Science and Technology Initiative
BISTIC	Bioinformatics Consortium (NIH OD)
BITS	Business Information Technology System
BJA	Bureau of Justice Assistance
BJS	Bureau of Justice Statistics
BL-3	Biosafety Level 3
BLA	Biologics License Application
BLIRC	Biomedical Library and Informatics Review Committee
BLM	Bureau of Land Management
BLS	Board on Life Sciences
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMDO	Ballistic Missile Defense Organization
BML	Biological Material License
BMMR	Biological Models and Materials Research
BMO	Business Management Office
BNA	Bureau of National Affairs
BNL	Brookhaven National Laboratory, Upton, NY (Department of Energy Organization)
BOA	Basic Ordering Agreement
BOG	Board of Governors, NIH

BOP	Federal Bureau of Prisons
BOR	Board of Regents
BOR	Bureau of Reclamation
BoS	Board of Survey
BPA	Blanket Purchase Agreement
BPD	Bureau of Public Debt
BPH	Benign Prostatic Hyperplasia
BPHC	Bureau of Primary Health Care
BPSRG	Basic Prevention Science Research Group
BRB	Benefits Review Board
BRCA	Breast Cancer
BRD	Biological Resource Division,
BRDPI	Biomedical Research and Development Price Index, measures real annual changes in the prices of items and services required for research and development (R&D) activities
BRFSS	Behavioral Risk Factor Surveillance System
BRG	Biometry Research Group
BRIN	Biomedical Research Infrastructure Network
BRMP	Biological Response Modifiers Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
BSC	Business Service Centers
BSI	Brief Symptom Inventory
BSL	Bio-Safety Level
BSSC	Behavioral and Social Sciences Coordinating Committee
BTP	Biotechnology Training Program
BTR	Biomedical Technology Resource

BTS	Bureau of Transportation Statistics
BVA	Board of Veterans Appeals

C

CAM	Complementary and Alternative Medicine
CBER	Center for Biologics Evaluation and Research
CBIAC	Chemical and Biological Defense Information Analysis Center
CBO	Congressional Budget Office
CBT	Computer-Based Training
CC	Warren Grant Magnuson Clinical Center, NIH
CCB	Configuration Control Board
CCB	Child Care Bureau
CCC	Commodity Credit Corporation
CCO	Chief Contracting Officer
CCR	Center for Career Resources (OD)
CCR	Center for Cooperative Resolution
CCR	Commission on Civil Rights
CCSS	Childhood Cancer Survivor Study
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation
CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDBG	Community Development Block Grants
CDC	Centers for Disease Control and Prevention, PHS (Public Health Service)
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research

CDFI	Community Development Financial Institutions
CDHR	Center for Devices and Radiological Health
CDMC	Central Data Management Center
CDMRP	Congressionally Directed Medical Research Program
cDNA	Complementary DNA
CDs	Communication Directors
CES	Central E-mail Service
CDP	Career Development Plan
CDR	Clinical Drug Request
CDUS	Clinical Data Update System
CDW	Consultant Days Worked
CEA	Council of Economic Advisers
CEC	Contractor Establishment Code
CEDR	Comprehensive Epidemiologic Data Resource
CEGS	Centers of Excellence in Genomic Science
CEL	Commercial Evaluation License
CEN	Bureau of the Census
CEPPO	Chemical Emergency Preparedness and Prevention Office
CEPS	Center for Earth and Planetary Studies
CEQ	Council on Environmental Quality
CERCLIS	Comprehensive Environmental Response, Compensation, & Liability Information System
CETEC	Topographic Engineering Center
CF	Consent Form
CFAR	Centers for AIDS Research
CFC	Combined Federal Campaign

CFDA	Catalog of Federal Domestic Assistance, a database that helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the database called the "CFDA number."
CFO	Chief Financial Office
CFOC	Chief Financial Officers Council
CFR	Code of Federal Regulations
CFS CRC	Chronic Fatigue Syndrome Cooperative Research Centers
CFSAN	National Center for Food Safety and Applied Nutrition
CGAP	Competitive Grant Application Process
CGH	Comparative genomic hybridization
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CHB	Community Health Branch (DOHS)
CHID	Combined Health Information Database
ChiMP	NIH Chimpanzee Management Program
CHIMP	Chimpanzee Health, Improvement, Maintenance and Protection Act
CHTN	Cooperative Human Tissue Network
CIAO	Critical Infrastructure Assurance Office
CIC	Consumer Information Center
CID	Center of Infectious Diseases (CDC)
CIDI	Composite International Diagnostic Interview (Clinical Trials Standard)
CIO	Chief Information Officer
CIPRA	Comprehensive International Program for Research on AIDS
CIS	Cancer Information Service
CISET	Committee on International Sciences, Engineering, and Technology
CIT	Center for Information Technology
CJD	Creutzfeldt-Jakob Disease

CLC	Community Liaison Council
CLIA	Clinical Laboratories Improvement Act
CLM	Council of Logistics Management
CMAB	Complaints Management and Adjudication Branch (OEO)
CMAP	Cancer Molecular Analysis Project
CMB	Comparative Medicine Branch
CMBD	Collection Management & Delivery Branch (DLS)
CME	Continuing Medical Education
CMHS	Center for Mental Health Services
CML	Chronic Myeloid Leukemia
CMO	Committee Management Officer, IC person responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act; responsible for developing committee charter, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures, etc.
CMP	Contract Management Program
CMP/HMO	Comprehensive Medical Plans/Health Maintenance Organizations
CMPP	Center for Nutrition Policy and Promotion
CMS	Centers for Medicare and Medicaid Services
CMSP	Cooperative Medical Sciences Program
CMV	Center for Minority Veterans
CNCRIT	Collaborative Network for Clinical Research on Immune Tolerance
CNS	Central Nervous System
CO	Contracting Officer
COB	Close of Business
COBRE	Centers of Biomedical Research Excellence
CoC	Commission on Cancer

CoC	Council of Councils
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COGA	Collaborative Study on the Genetics of Alcoholism
COI	Conflict of Interest
COLA	Cost of Living Allowance
CONSER	Cooperative Online Serials
COOG	Continuity of Operations Group
COOP	Continuity of Operations Plan
COP	Continuation of Pay
COP	Costal Ocean Program
COPR	Council of Public Representatives (serves NIH Director)
COPS	Office of Community Oriented Policing Services
COPTRG	Community Oncology and Prevention Trials
COR	Career Opportunities in Research Education and Training
COSEPUP	Committee on Science Engineering and Public Policy
COTA	Career Opportunities Training Agreement (HHS)
COTS	Commercial Off-The-Shelf Software Products
CPA	Cooperative Project Assurance
CPAF	Cost Plus Award Fee
CPDF	Central Personnel Data File
CPE	Continuing Professional Education
CPFP	Cancer Prevention Fellowship Program
CPI	Consumer Price Index
CPIF	Cost Plus Incentive Fee

CPMS	Defense Civilian Personnel Management Service
CPO	Corrections Program Office
CPS	Contractor Performance System
CPS	Center for Prevention Services (CDC)
CPSC	Consumer Product Safety Commission
CR	Continuing Resolution
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRC	Civil Rights Center
CRC	New Clinical Research Center
CRF	Case Report Form (Source Document for Clinical Studies)
CRIB	Central Institutional review Board
CRIC	Chronic Renal Insufficiency Cohort
CRIS	Clinical Research Information System
CRISP	Computer Retrieval of Information on Scientific Programs, A searchable biomedical database of federally supported proposed research conducted at universities, hospitals, institutions, etc.
CRL	Charles River Laboratories
CRM	Customer Relations Manager
CRO	Contract Research Organization
CRP	Conference Room Pilot
CRP	Conservation Reserve Program
CRS	Congressional Research Service
CRS	Clinical Research Scholar
CRS	Community Relations Service
CRTA	Cancer Research Training Award

CRTP	Clinical Research Training Program
CRVP	Clinical Research Volunteer Program
CS	Contract Specialist
CSAC	Central Services Advisory Committee
CSAP	Center for Substance Abuse Prevention
CSAT	Center for Substance Abuse Treatment
CSB	Customer Service Branch (DMAPS)
CSB	Chemical Safety and Hazard Investigation Board
CSD	Client Services Division
CSE	Office of Child Support Enforcement
CSI	Center for the Study of Intelligence
CSR	Center for Scientific Review
CSREES	Cooperative State Research, Education, and Extension Service
CT	Computed Tomography
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTC	Common Toxicity Criteria
CTEP	Clinical Therapeutic Evaluation Program
CTEP	Cancer Therapy Evaluation Program
CTN	National Drug Abuse Treatment Clinical Trials Network
CTP	Community Treatment Program
CTSA	Clinical and Translational Science Awards
CTSU	Clinical Trials Support Unit
CU	Coordinating Unit
CUAP	College and University Affiliations Program

Cumulus SPMS	Cumulus Slide/Presentation Management System
CVS	Cardiovascular Sciences
CVS	Chorionic Villus Sampling
CWC	Chemical Weapons Convention
CWD	Chronic Wasting Disease
CY	Calendar Year

D

D&A	Design and Analysis Workgroup
D&B	Dun & Bradstreet Number
DAP	Division of Acquisition Programs, OLAO
DARPA	Defense Advanced Research Projects Agency
DASAM	Deputy Secretary for Administration and Management
DASPA	Division of Advanced Studies and Policy Analysis
DB	Design Branch (DMAPS)
DBASSE	Division of Behavioral and Social Sciences and Education
DBBD	Division of Biological Basis of Disease
DBDR	Division of Blood Diseases and Resources
DBPS	Division of Bioengineering and Physical Science
DBT	Division of Biomedical Technology
DCA	Division of Cost Allocation
DCAA	Defense Contract Audit Agency
DCCT	Diabetes Control and Complications Trial
DCIS	Department Contract Information System
DCLG	Director’s Consumer Liaison Group

DCM	Division of Comparative Medicine
DCMC	Defense Contract Management Command
DCMS	Division of Mail and Courier Services (ORS)
DCPS	Division of Clinical and Population Based Studies
DCR	Division of Career Resources, OHRM, NIH
DCR	Division of Clinical Research
DCRT	Division of Computer Research and Technology (now CIT)
DDC	Defense Distribution Center
DDER	Deputy Director of Extramural Research, NIH
DDIR	Deputy Director for Intramural Research
DDKR	Drug Delivery & Kinetics Resource (DBPS)
DDM	Deputy Director for Management
DDN	Division of Digestive Diseases and Nutrition, NIDDK
DDP	Diamminedichloroplatinum
DEA	Division of Extramural Activities, NIDDK
DEC	Deputy Ethics Counselor
DeCA	Defense Commissary Agency
DEIS	Division of Extramural Information Systems
DELPRO	Delegated Procurement System
DEM	Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
DEMS	Division of Events Management Services (PES or P&ES)
DEPC	Division of Emergency Preparedness & Coordination
DEPS	Division of Epidemiology and Population Studies
DERT	Division of Extramural Research and Training
DES	Division of Engineering Services

DFAS	Defense Finance and Accounting Service (sends out DHHS/NIH W2s for honorariums, etc.)
DFM	Division of Financial Management
DHHS	Department of Health and Human Services
DHRS	Division of Human Resource Systems, OHRM, NIH
DHVD	Division of Heart and Vascular Diseases
DICOM	Digital Imaging and Communications in Medicine
DINFOS	Defense Information School
DIR	Division of Intramural Research, NIDDK
DITA	Division of Information Technology Acquisition, OLAO (also known as NITAAC)
DITR	Division of International Training and Research
DLD	Division of Lung Diseases
DLS	Division of Library Services
DLS	Division of Logistics Services, OLAO
DLT	Digital linear tape
DM	Data management
DMAPS	Division of Medical Arts and Printing Services
DMAS	Data Management and Analysis Subcommittee
DMCM	Division of Molecular and Cellular Mechanisms
DMCS	Division of Mail and Courier Services
DMDC	Defense Manpower Data Center
DMID	Division of Microbiology and Infectious Diseases
DMS	Division of Management Services
DNA	Deoxyribonucleic Acid
DOHS	Division of Occupational Health and Safety
DORRA	DLA Office of Operations Research and Resource Analysis

DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPPS	Division of Personal Property Services, OLAO
DPS	Division of Physiological Systems
DPSM	Division of Physical Security Management
DRA	Division of Research Acquisition, OLAO
DRI	Division of Research Infrastructure
DRR	Division of Receipt and Referral
DRS	Division of Radiation Safety
DRSB	Diagnostic & Research Services Branch
DS	Division of Safety, Office of Research Services
DSEIS	Division of Scientific Equipment and Instrumentation Services (ORS)
DSFM	Division of Space and Facility Management
DSMB	Data and Safety Monitoring Board
DSM-IV	Diagnostic & Statistical Manual of Mental Disorders – 4th Edition
DSO	Division of Security Operations
DSS	Division of Support Services
DSSA	Division of Station Support Acquisition, OLAO
DTIC	Defense Technical Information Center
DTM	Department of Transfusion Medicine (ORS)
DTP	Developmental Therapeutics Program
DTTS	Division of Travel and Transportation Services
DUNS	Data Universal Numbering System
DVR	Division of Veterinary Resources
DW	Data Warehouse
DWD	Division of Workforce Development

E

EA	Expanded Authorities
EA	Enterprise Architecture
EAC	External Advisory Committee
EACC	External Affairs Coordinating committee
EAP	Employee Assistance Program
EBSA	Employee Benefits Security Administration
EC	Executive Committee
EC	European Commission
ECA	Executive Committee for Acquisition
ECA	Bureau of Educational and Cultural Affairs
ECAB	Employees' Compensation Appeals Board
ECB	Electronic Council Book
ECFMG	Educational Commission for Foreign Medical School Graduates
ECIE	Executive council on Integrity and Efficiency
ECL	Executive Committee on Logistics
ECOSOC	Economic and Social Council
ECP	Emergency Conservation Program
ECR-LRP	Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
EDGAR	Electronic Data Gathering, Analysis, and Retrieval
EDI	Electronic Data Interchange
EDIC	Epidemiologic Cohort Study
Edison	Extramural Invention Information Management System
EDRG	Early Detection Research Group

EDRN	Early Detection Research Network
EEO	Equal Employment Opportunity
EEOC	Equal Employment Opportunity Commission
EES	Enterprise E-Mail System
EHP	Environmental Health Perspectives
EHRP	Enterprise Human resources and Payroll System
EIA	Energy Information Administration
EIN	Entity Identification Number
EIR	Employee Invention Report
EIS	Epidemic Intelligence Service
ELS	Earnings and Leave Statement
ELSI	Ethical, Legal and Societal Implications
EL-TRAINS	Electronic Logistics Training & Support Network
EM	Office of Environmental Management
EML	Environmental Measurement Laboratory
EMPSB	Events Management Program Support Branch (DEMS)
ENC	Eisenhower National Clearinghouse
ENR	Endocrinology and Reproductive Sciences
ENS	Early Notification System
EO	Executive Order
EOB	Editorial Operations Branch
EOC	Ethics Oversight Committee
EOD	Entrance on Duty
EOIR	Executive Office for Immigration Review
EOP	Executive Office of the President

EOUSA	Executive Office for United States Attorneys
EP	Extramural Programs
EPMC	Extramural Program Management Committee
EPN	Executive Plaza North (6130 Executive Blvd.; Rockville, MD 20852)
EPRU	Enteric Pathogens research Unit
EPS	Executive Plaza South (6120 Executive Blvd.; Rockville, MD, 20852)
EPSCoR	Experimental Program to Stimulate Competitive Research
EPSS	Electronic Performance Support Systems
eRA	Electronic Research Administration; responsible for IMPAC II
ERDA	Energy Research and Development Administration
EREN	Energy Efficiency and Renewable Energy Network
ERIC	Educational Resources Information Center
EROD	Educational Resource Organizations Directory
ERP	Extramural Research Program
ERS	Economic Research Service
ERSB	Equipment Rental & Sakes Branch (DSEIS)
ES	Executive Secretariat (NIH)
ESA	Extramural Scientist Administrator
ESA	Employment Standards Administration
ESA	Economics and Statistics Administration
ESDIM	Environmental Services Data and Information Management
ESG	Executive Staffing Group (REPS, PMB, NCI)
eSNAP	Electronic Streamlined Non-competing Award Process
ETA	Employment and Training Administration
ETSO	Employee Transportation Services Office

F

F & A	Facilities and Administrative Cost
F Awards	Fellowship Awards
FACA	Federal Advisory Committee Act
FAES	Foundation for Advanced Education in the Sciences
FAI	Fair Act Inventory
FAIR Act	Federal Activities Inventory Reform Act
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FARB	Funding Advisory Review Board
FASAB	Federal Accounting Standards Advisory Board
FASEB	Federation of American Societies for Experimental Biology
FCC	Federal Communications Commission
FCOI	Financial Conflict of Interest
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration (PHS)
FDP	Federal Demonstration Partnership
FECA	Federal Employees' Compensation Act
FEGLI	Federal Employees' Group Life Insurance
FEHBP	Federal Employees' Health Benefit Program
FEMA	Federal Emergency Management Agency
FERC	Federal Energy Regulatory Commission
FERS	Federal Employees' Retirement System
FFLA	Family Friendly Leave Act
FIC	John E. Fogarty International Center

FICA	Federal Insurance Contributions Act (Social Security)
FIRST	First Independent Research Support and Transition Award
fMRI	Functional Magnetic Resonance Imaging
FMS	Financial Management Service
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act of 1966, amended 1986
FRB	Federal Reserve Board
FRS	Federal Reserve System
FTC	Federal Trade Commission
FTE	Full Time Equivalent
FTTP	Full-Time Training Position
FWA	Federal Wide Assurance
FY	Fiscal Year (October 1 – September 30)
FYI	For Your Information

G

GAO	General Accounting Office, Congress
GBV-C	Hepatitis G (GB Virus-C)
GCRC	General Clinical Research Center
GDB	Human Genome Database
GH	Growth Hormone
GM	Grants Management
GMB	Grants Management Branch Office
GME	Graduate Medical Education
GMO	Grants Management Officer

GMS	Grants Management Specialist
GPA	Grade Point Average
GPEA	Government Paperwork Elimination Act of 1998
GPO	Government Printing Office
GPRA	Government Performance Results Act of 1993
GPS	Global Positioning Satellite System
GRE	Graduate Record Examinations
GS	General Schedule
GSA	General Services Administration
GTA	Grants Technical Assistant
GWAC	Government-Wide Acquisition Contract

H

HAART	Highly Active Antiretroviral Therapy
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HDR-LRP	Loan Repayment Program for Health Disparities Research
HEM	Hematology Study Section
hESC	Human Embryonic Stem Cells
HHMI	Howard Hughes Medical Institute
HHS	Health and Human Services (Department of)
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization

HPV	Human Papillomavirus
HQ	Headquarters
HRSA	Health Resources and Services Administration, PHS
HRT	Hormone Replacement Therapy
HSA	Health Scientist Administrator
HSRAC	Human Subjects Research Advisory Committee
HSRB	Human Subjects Review Board
HSV	Herpes Simplex Virus
HTML	Hypertext Markup Language

I

IACUC	Institutional Animal Care and Use Committee
IAG	Interagency Agreement
IAR	Internet Assisted Review
IBC	Institutional Biosafety Committee
IC	Institute and Center (NIH)
ICC	Interstate Commerce Commission
ICD	Institutes/Centers/Divisions
ICF	Informed Consent Form
ID	Identification
IDE	Investigational Device Exemption (FDA)
IDeA	Institutional Development Award Program (NCRR)
IDIQ	Indefinite Delivery Indefinite Quality Contract
IDM	Infectious Diseases and Microbiology
iEdison	NIH's Extramural Electronic Invention Reporting system

IFCN	Integrative, Functional and Cognitive Neuroscience
IG	Inspector General
IHS	Indian Health Service, PHS
IMA	Internal Monitoring Board
IMAGE	Integrated Molecular Analysis of Genomes and their Expression
IMF	International Monetary Fund
IMPAC	Integrated Management, Planning, Analysis and Coordination (Data System)
IMPAC II	Information for Management, Planning, Analysis, and Coordination (grants data system)
IMS/ADB	Information Management System/Administrative Data Base System (DELPRO)
IND	Investigational New Drug Application (FDA)
INS	Immigration and Naturalization Service (now the United States Citizenship and Immigration Services)
IO	Information Officer
IOM	Institute of Medicine, NAS
IP	Intellectual Property
IPC	Incidental Patient Contact
IPF	Institutional Profile File Number
IRA	Individual Retirement Account
IRACDA	Institutional Research and Academic Career Development Award
IRB	Institutional Review Board
IRG	Integrated Review Group, a cluster of study sections responsible for review of grant applications in scientifically related areas; sections share common intellectual and human resources.
IRM	Information Resources Management
IRP	NIH Intramural Research Program
IRPG	Interactive Research Project Grant
IRTA	Intramural Research Training Award or Agreement

ISO	International Organization for Standardization
ISSO	Information Systems Security Office
IT	Information Technology
ITAS	Integrated Time and Attendance System
ITB	Information Technology Branch
ITC	United States International Trade Commission

J

JAX	The Jackson Laboratory
JHU	Johns Hopkins University
JOFOC	Justification for Other than Full and Open Competition
Just-in-time	Grant application timeframe that requires applicants to send some information to NIH only if an award is likely. Also used for other support information, and other items, including: certification of IRB approval, Federal wide assurance, IACU certification, and letter stating key personnel have been trained in protecting human subjects

K

K Awards	Mentored and Career Development Awards
KSA	Knowledge, Skills and Ability Form
KSASF	Knowledges, Skills, Abilities Supplemental Form (NIH-2252-3)
KUH	Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

L

LABS	Laboratory Automated Bibliographic System
LAN	Local Area Network
LAO	Leave Approving Official

LAS	Laboratory Animal Sciences
LAT	Laboratory Animal Technician (AALAS Certified)
LATG	Laboratory Animal Technologist (AAALAS Certified)
LCM	Laser Capture Microdissection
LI	Lead Investigator
LOC	Library of Congress
LOCIS	Library of Congress Information System
LOE	Level of Effort
LOI	Letter of Intent
LRP	Loan Repayment Program (NIH)
LWOP	Leave Without Pay

M

MA	Master Agreement
MAC	Multiple Award Contract
MACs	Multiple Agency Contracts
MARC	Minority Access to Research Career Program
MBRS	Minority Biomedical Research Support
MC	Manual Chapter
MCDN	Molecular, Cellular and Developmental Neuroscience
MCP	NIH Management Cadre Program
MCR	Management Control Review
MCSB	Mail Customer Service Branch (DMCS)
MCRU	Metabolic Clinical Research Unit (in NIH Clinical Center)
MEDLINE/ PUBMED	National Library of Medicine's Database for Scientific Publications

MEO	Most Efficient Organization
MERIT	Method to Extend Research in Time Award
MeSH	Medical Subject Headings
MF	NIH Management Fund
MHC	Major Histocompatibility Complex
MHPF	Minority Health Professionals Foundation
MI	Minority Institutions
MIGA	Multilateral Investment Guarantee Agency
MIS	Medical Information System
ML	Military Leave
MM	Medical Monitor
MODY	Maturity Onset Diabetes of the Young
MORE	Minority Opportunities in Research
MOU	Memorandum of Understanding
MOU/MOA	Memorandum of Understanding/Memorandum of Agreement
MPA	Multiple Project Assurance
MPP	Merit Program Plan (NIH)
MPW	Medical Pathological Waste
MRA	Minimum Retirement Age
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
M-RISP	Minority-Research Infrastructure Support Program
mRNA	Messenger RNA
MRS	Magnetic Resonance Spectroscopy
MSDS	Material Safety Data Sheet

MSPB	Merit Systems Protection Board
MTA	Material Transfer Agreement
MTCT	Mother-to-Child Transmission

N

N/A	Not Applicable/Not Available
NAFTA	North American Free Trade Agreement
NAHFE	National Association of Hispanic Federal Executives
NARA	National Archives and Records Administration
NARCH	Native American Research Centers for Health
NARFE	National Association of Retired Federal employees
NAS	National Academy of Sciences (U.S.)
NBAC	National Bioethics Advisory Commission
NBII	National Biological Information Infrastructure
NBN	National Biospecimen Network
NBRSS	NIH Business and Research Support System
NBS	New Business Systems/NIH Business System
NCATS	National Center for Advancing Translational Sciences
NCBI	National Center for Biotechnology Information
NCC	National Coordinating Center for Telecommunications
NCCAM	National Center for Complementary and Alternative Medicine (NIH)
NCCDPHP	National Center for Chronic Disease and Prevention Health Promotion (CDC)
NCCIC	National Child Care Information Center
NCCLS	National Committee for Clinical Laboratory Standards
NCD	National Council on Disability

NCEH	National Center for Environmental Health (CDC)
NCES	National Center for Education Statistics
NCHS	National Center for Health Statistics
NCI	National Cancer Institute (NIH)
NCICAS	National Cooperative Inner-City Asthma Study
NCIPC	National Center for Injury Prevention and Control (CDC)
NCRR	National Center for Research Resources (dissolved as of December 23, 2011)
NCSDR	National Center on Sleep Disorders Research
NCTR	National Center for Toxicological Research
NCUA	National Credit Union Administration
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDDKDAC	National Diabetes and Digestive and Kidney Diseases Advisory Council
NDIC	National Drug Intelligence Center
NDRI	National Disease Research Interchange
NED	NIH Enterprise Directory
NEI	National Eye Institute (NIH)
NFT	Notification of Foreign Travel
NGA	Notice of Grant Award (also NoGA) [see NOGA p 36/59]
NGO	Non-Government Organization
NHGRI	National Human Genome Research Institute (NIH)
NHIC	National Health Information Center
NHLBI	National Heart, Lung, and Blood Institute (NIH)
NHP	Nonhuman Primate
NHRPAC	National Human Research Protection Advisory Committee

NHSC	National Health Sciences Scholarship
NIA	National Institute on Aging (NIH)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (NIH)
NIAID	National Institute of Allergy and Infectious Disease (NIH)
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH)
NIBIB	National Institute of Biomedical Imaging and Bioengineering (NIH)
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDCD	National Institute on Deafness and Other Communication Disorders (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIH DW	NIH Data Warehouse
NIHAC	The National Institutes of Health Animal Center (Poolesville, MD)
NIHITS	NIH Integrated Training System
NIHTC	National Institutes of Health Training Center
NIMH	National Institute of Mental Health (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
NINR	National Institute of Nursing Research (NIH)
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIST	National Institute of Standards and Technology

NLAES	National Longitudinal Alcohol Epidemiologic Survey
NLM	National Library of Medicine (NIH)
NLT	Not Later Than
NMA	National Medical Association
NMR	Nuclear Magnetic Resonance
NMS	Nutritional and Metabolic Sciences
NOA	Nature of Action
NOGA	Notice of Grant Award [see NoGA prior page at NGA]
Non-FTE	Non Full-time Equivalent
NOTA	National Organ Transplant Act
NPEBC	National Programs of Excellence in Biomedical Computing
NPRC	National Primate Research Center
NREN	National Research and Education Network
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRFC	Not Recommended for Further Consideration
NRL	Naval Research Laboratory
NRSA	National Research Service Award (e.g., T32, F32)
NS	No Score (lower 50% of grants in study section)
NSF	National Science Foundation
NSRG	Nutritional Science Research Group
NSTC	National Science and Technology Center
NSTL	National Space Technology Laboratories
NTE	Not To Exceed
NTIA	National Telecommunications and Information Administration
NTIS	National Technical Information Service

NTP	National Toxicology Program

O

OA	Office of Administration
OACU	Office of Animal Care and Use
OAM	Office of Administrative Management (OD)
OAMP	Office of Acquisition Management and Policy, OA
OAPP	Office of Adolescent Pregnancy Programs (OASH)
OAR	Office of AIDS Research
OASDI	Old Age Survivor Disability Insurance
OASH	Office of the Assistant Secretary for Health, PHS
OASPA	Office of the Assistant Secretary for Public Affairs
OB	Office of Budget (NIH OD)
OBA	Office of Biotechnology Activities (NIH OD)
OBL	Office of Business Liaison
OBSF	Office of Business Systems & Finance (OD)
OBSSR	Office of Behavioral and Social Sciences Research (NIH OD)
OC	Office of Communications
OCAB	Office of the Assistant Secretary for Health, PHS
OCC	Operations Coordinating Committee
OCCC	Office of Clinical Center Communications
OCL	Office of Community Liaison (NIH OD)
OCPL	Office of Communications & Public Liaison
OD	Office of the Director, NIH
ODA	Official Duty Activities

ODEO	Office of the Director Executive Office (NIH OD)
ODEP	Office of Disability Employment Policy
ODP	Office of Disease Prevention (NIH OD)
ODS	Office of Dietary Supplements (NIH OD)
OE	Office of Education (NIH OD)
OEEO	Office of Equal Employment Opportunity (NIH OD)
OEO	Office of Equal Opportunity
OEODM	Office of Equality, Opportunity & Diversity Management
OEP	Office of Extramural Programs, OER, OD, NIH
OER	Office of Extramural Research, OD, NIH
OFACP	Office of Federal Advisory Committee Policy (NIH OD)
OFCCP	Office of Federal Contract Compliance Programs
OFM	Office of Financial Management
OFRM	Office of Financial Resources Management
OGC	Office of the General Counsel (NIH OD)
OGE	Office of Government Ethics
OHASIS	Office of Health and Safety Information System
OHER	Office of Health and Environmental Research
OHR	Office of Human Resources (NIH OD)
OHRM	Office of Human Resource Management (NIH OD)
OHRP	Office for Human Research Protections
OHS	Office of Healthy Start (HRSA)
OHSR	Office of Human Subjects Research
OIB	Office of Information Branch
OIG	Office of the Inspector General (USDA)

OIIA	Office of Intergovernmental and Interagency Affairs
OIR	Office of Intramural Research (NIH OD)
OIT	Office of Information Technology
OLAO	Office of Logistics and Acquisition Operations
OLAW	Office of Laboratory Animal Welfare, OER, OD, NIH
OLM	Office of Logistics Management
OLPA	Office of Legislative Policy and Analysis (NIH OD)
OLRS	Office of Loan Repayment and Scholarship (NIH OD)
OM	Office of Management (NIH OD)
OMA	Office of Management Assessment (NIH OD)
OMAR	Office of Medical Applications of Research (NIH OD)
OMB	Office of Management and Budget (White House)
OMBS	Office of Medical Board Services
OMH	Office of Minority Health (OASH)
OMS	Occupational Medical Services (DOHS)
ONC	Oncological Sciences
OPASI	Office of Portfolio Analysis and Strategic Initiatives (dissolved October 2008)
OPDIV	Operating Division (HHS)
OPEC	Office of Prevention, Education, and Control
OPERA	Office of Policy for Extramural Research Administration
OPF	Official Personnel File
OPHS	Office of Public Health and Science
OPL	Offices of Public Liaison (NIH OD)
OPM	Office of Personnel Management
OPRR	Office of Protection from Research Risks

ORA	Office of Reports and Analysis, OER, OD, NIH
ORD	Office of Rare Diseases (NIH OD)
ORI	Office of Research Integrity, HHS
ORIM	Office of Information Resources Management
ORS	Office of Research Services (NIH OD OM)
ORWH	Office of Research on Women's Health, OD, NIH
OS	Office of the Secretary
OSA	Office of Scientific Affairs, OER, OD, NIH
OSC	Office of Strategic Coordination, DPCPSI, OD, NIH
OSD	Office of the Scientific Director
OSE	Office of Science Education (NIH OD)
OSHA	Occupational Safety and Health Administration
OSHRC	Occupational Safety and Health Review Commission
OSMP	Office of Strategic Management and Planning (NIH OD)
OSP	Office of Science Policy (NIH OD)
OSPA	Office of Science Policy Analysis
OSPP	Office of Science Policy and Planning
OST	Office of Science and Technology
OSTI	Office of Scientific and Technical Information
OSTP	Office of Science and Technology Policy (White House)
OT	Overtime
OTA	Office of Technology Assessment
OTD	Office of Technology Development
OTS	Omega Travel Service (NIH Travel Agent)
OTT	Office of Technology Transfer

OUTPT	Outpatient
OWH	Office on Women's Health

P

P/TRP	Promotion/Tenure Review Panel
PA	Program Announcement
PA	Purchasing Agent
PAM	Office of Acquisition and Property Management
PAR	Program Announcement with special receipt or review
PART	Program Assessment Rating Tool (OMB)
PAS	Program Announcement with Set-aside funds
PCA	Physicians Comparability Allowance
PCBE	President's Council on Bioethics
PD	Position Description
PDF	Portable Document Format
PET	Positron Emission Tomography
PETA	People for the Ethical Treatment of Animals
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (U.S.)
PHS OWH	U.S. Public Health Service's Office on Women's Health
PHTN	Public Health Training Network
PI	Principal Investigator
PIA	Procurement Integrity Act
PIN	Personal Identification Number
PKU	Phenylketonuria

PLC	Program Leadership Committee
PMCID	PubMed Central Identification
PMI	Presidential Management Intern
PMIS	Property Management Information System
PMO	Property Management Officer
PO	Program Official
PO	Project Officer (For a Grant or Contract)
PO	Purchase Order
Post-Doc	Post-Doctoral Fellow
PP	Pay Period
PPE	Pay Period Ending
PPP	Public Private Partnerships
PPS	Pathophysiological Sciences
PR	Public Relations
PRB	Protocol Review Board
PRC	Processing Resource Centers
Pre-Doc	Pre-Doctoral Fellow
PRG	Progress Review Groups
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Project EXPORT	Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training
PROTRACK	Clinical Center Protocol Tracking Database
PrP	Prion Protein
PRPL	Patient Recruitment and Public Liaison Office
PRRR	Program Review Report Record

PRS	Protocol Review Subcommittee
PSC	Program Support Center
PSC	Publications Subcommittee
PSO	Professional Service Order
PSP	Physician Special Pay (Title 38)
PTSD	Post-Traumatic Stress Disorder
PWS	Performance Work Statement

Q

Q&A	Questions and Answers
QA	Quality Assurance
QALY	Quality-Adjusted Life Years
QAP	Quality Assurance Program
QAS	Quality Assurance Subcommittee
QC	Quality Control
QRB	Quality Review Board
QSI	Quality Step Increase

R

R&D	Research & Development
R&W	Recreation and Welfare
R01	Standard NIH Research Project Grant
R34	Investigator-Initiated Clinical Trial Planning and Implementation Grants
R56	Grant allowing an interim award so principal investigator can continue while reapplying for an R01 grant. Also enables new investigators to gather preliminary data to improve their grant applications. (Bridge Award)

RA	Research Assistant
RAC	Recombinant-DNA Advisory Committee
RAID	Rapid Access to Intervention Development
RAL	Restored Annual Leave
RALAT	Registered Assistant Laboratory Animal Technician
RAO	Regulatory Affairs Officer
RCC	Research Coordination Council (Department-wide)
RCDA	Research Career Development Award (K-series awards)
RCDC	Research, Condition, and Disease Categorization
RCR	Responsible Conduct of Research
RCRII	RCMI Clinical Research Infrastructure Initiative
RCT	Randomized Controlled Trial
rDNA	Recombinant DNA
RePORT	NIH Research Portfolio Online Reporting Tools
RePORTER	RePort Expenditures and Results
RFA	Request for Application (request for grant applications for a research area)
RFC	Request For Contract
RFI	Request for Information
RFIP	Research Facilities Improvement Program
RFP	Request For Proposal (request for contract proposal for a project)
RFQ	Request for Quotation
RIF	Reduction In Force
RIMS	Robocom Inventory Management System
RISE	Research Initiative for Scientific Enhancement
RM	Roadmap

RMA	Risk Management Agency
RMS	Research Management Support
RNA	Ribonucleic Acid
RNAi	RNA interference
RPC	Review Policy Committee
RPG	Research Project Grant
RPHB	Risk, Prevention, and Health Behaviors
RPPR	Research Program Performance Report
RRTC	Regional Research and Training Center
RSA	Rehabilitation Services Administration
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSOB	Radiation Safety Operations Branch (DRS)
RSUM	Research Supplements for Underrepresented Minorities

S

SAC	Simplified Acquisition Committee
SAE	Serious Adverse Event
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SB	Small Business
SBA	U.S. Small Business Administration
SBIR	Small Business Innovation Research
SBO	Small Business Office
SBRS	Senior Biomedical Research Service
SBS	Small Business Specialist

SBSA	Small Business Set-Aside
SC	Steering Committee
SCD	Service Computation Date
SCORE	Support of Continuous Research Excellence
SCR	Special Council Review
SD	Scientific Director
SDB	Small Disadvantaged Business
SEER	Surveillance, Epidemiology, and End Results
SE	Special Emphasis
SEP	Special Emphasis Panel (an SRG convened for a single meeting)
SES	Senior Executive Service
SF	Standard Form
SF	Staff Fellow
SIG	Shared Instrumentation Grant
SIMS	Scientific Initiative Management System
SIP	Summer Internship Program in Biomedical Research
SLA	Simple Letter of Agreement
SMSA	Small Business & Minority Business Set Aside
SNAP	Streamlined Noncompeting Award Process
SNEM	Social Science, Nursing, Epidemiology, and Methods
SNMA	Student National Medical Association
SNOMED	Systemized Nomenclature of Medicine
SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
SNPs	Single Nucleotide Polymorphisms
SO	Signing Official

SOP	Standard Operating Procedure
SOW	Statement Of Work
SPA	Single Project Assurance
SPF	Specific-pathogen free
SPIN	Shared Pathology Informatics Network
SPORE	Specialized Program of Research Excellence
SRAs	Scientific Review Administrator (an NIH scientist administrator in charge of review and advisory groups; now called SROs)
SRB	Surgery, Radiology, and Bioengineering
SRB	Scientific Review Board
SREA	Scientific Review Evaluation Awards
SRFP	Summer Research Fellowship Program
SRG	Scientific Review Group (performs initial scientific merit review of grant application & contract proposals; also called Initial Review Group (IRG) when pertaining to grant applications)
SROs	Scientific Review Officer (manages the peer review process for grant applications and contract proposals; designated Federal official responsible for the peer review meeting; major focus is on scientific rather than administrative activities; former title was SRA)
SSB	Support Services Branch (DP)
SSEB	Source Selection Evaluation Board
SSF	Senior Staff Fellow
SSF	Service and Supply Fund
SSN	Social Security Number
SSS	Special Study Section
STD	Sexually Transmitted Disease
STDCRC	Sexually transmitted Disease Cooperative Research Centers
STDCTU	Sexually Transmitted Disease Clinical Trials Unit
STEP	Staff Training in Extramural Programs
STI	Scientific and Technical Information

STTR	Small Business Technology Transfer
SV	Student, or Special Volunteer

T

T&A	Time and Attendance
TAIMS	Time and Attendance Information Management System
TEHIP	Toxicology and Environmental Health Program
TIA	Time Off Incentive Award
TIG	Time In Grade
TIN	Payer Identification Number Tax
TK	Timekeeper
TMA	Tissue Microarray
TMJ	Temporomandibular joint
TO	Task Order
TOD	Tour of Duty
TOXNET	Toxicology Data Network
TQM	Total Quality Management
TSC	Training Subcommittee
TSP	Thrift Savings Plan
TTB	Technology Transfer Branch
TX	Treatment

U

U.S.C.	United States Code
UMLS	Unified Medical Language System

URC	User Resource Center
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USIA	United States Information Agency
USOPM	United States Office of Personnel Management
USUHS	Uniformed Services University of Health Sciences

V

VA	Veterans Administration
VA	Department of Veterans Affairs
VF	Visiting Fellow
VLTP	Voluntary Leave Transfer Program
VRC	Vaccine Research Center
VRP	Veterinary Resources Program
VS	Visiting Scientist
VSOF	Visual Status of Funds

W

WAG	Widely Attended Gathering
WFCL	Work and Family Life Center
WG	Wage Grade
WGI	Within-Grade Increase
WHI	Women's Health Initiative
WHO	World Health Organization, United Nations

WTO	World Trade Organization
WWW	World Wide Web
WYLBUR	Interactive system providing simultaneous service to more than 825 terminals or microcomputers.

X

X-Train	Trainee Activities System

Y

YTD	Year To Date

Z

ZIP (Code)	Zone Improvement Plan

National Institute of Diabetes and Digestive and Kidney Diseases Mission, Overview, and History

From 1950 until May 19, 1972, the Institute was known as the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, it was the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, it was the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

Overview

The NIDDK supports a wide range of medical research through grants to universities and other medical research institutions across the country. The Institute also supports government scientists who conduct basic, translational, and clinical research across a broad spectrum of research topics and serious, chronic diseases and conditions related to the Institute's mission. In addition, the NIDDK supports research training for students and scientists at various stages of their careers and a range of education and outreach programs to bring science-based information to patients and their families, health care professionals, and the public.

External research funded by the NIDDK is organized into three scientific program divisions:

Diabetes, Endocrinology, and Metabolic Diseases

Digestive Diseases and Nutrition

Kidney, Urologic, and Hematologic Diseases

NIDDK's overarching principles in moving research forward include:

- Maintaining a vigorous, investigator-initiated research portfolio that supports cross-cutting science that can be broadly applied to many disease-specific research areas.
- Supporting pivotal clinical studies and trials, with a focus on substantial participation from minority and underserved groups.
- Preserving a stable pool of talented new investigators.
- Fostering exceptional research training and mentoring opportunities.
- Ensuring that science-based health information reaches patients, their families, healthcare providers and the public through effective communications and outreach activities.

Important Events in NIDDK History

August 15, 1950 – President Harry S. Truman signed the Omnibus Medical Research Act into law establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine

Institute and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases.

November 15, 1950 – The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

1959 – Dr. Arthur Kornberg, former chief of the Institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

The Institute initiated an intramural research program in gastroenterology and launched an intramural research program in cystic fibrosis with the establishment of the Pediatric Metabolism Branch.

1961 – Laboratory-equipped, mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1968 – The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute, who reported his celebrated partial cracking of the genetic code while an NIAMD scientist (1957-1962).

November 1970 – The Institute celebrated its 20th anniversary. U.S. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, as well as past and present Institute National Advisory Council members.

May 19, 1972—The Institute name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases.

October 1972 – Christian B. Anfinsen, chief of the Institute's Laboratory of Chemical Biology, shared a Nobel Prize with 2 other American scientists for his demonstration of one of the most important simplifying concepts of molecular biology, that the 3-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of this research cited by the award was performed while with NIH.

September 1973 – The Institute's diabetes centers program was initiated with the establishment of the first Diabetes-Endocrinology Research Centers.

November 1975 – After 9 months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the *Long-Range Plan to Combat Diabetes*, to Congress. Recommendations encompassed expansion and coordination of diabetes and related research programs; creation of a diabetes research and training centers program; acceleration of efforts in diabetes health care, education, and control programs; and establishment of a National Diabetes Advisory Board.

April 1976 – After a year of study and public hearings, the National Commission on Arthritis and Related Musculoskeletal Diseases issued *The Arthritis Plan*—its report to Congress. The report called for increased arthritis research and training programs, multipurpose arthritis centers, epidemiologic studies and data systems in arthritis, a National Arthritis Information Service, and a National Arthritis Advisory Board.

October 1976 – Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the Institute. This advance has proven to be a scientific and clinical landmark in detection and control of viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977 – The NIH Director established a trans-NIH program for diabetes, with lead responsibility in NIAMDD.

September 1977 – Over $5 million in grants was awarded to 5 institutions to establish Diabetes Research and Training Centers.

October 1977 – In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the Institute to collect, analyze, and disseminate data on this disorder to scientific and public health policy and planning associations.

December 1977 – Institute grantees Dr. Roger C.L. Guillemin and Dr. Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist, Dr. Rosalyn S. Yalow. Guillemin and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

December 1978 – A study of cystic fibrosis focused on the need for future research activities, including increased support for clinical and basic research, expansion of specialized cystic fibrosis research resources, emphasis on training of scientific personnel, and coordination of public and private cystic fibrosis research activities.

1978 – The NIDDK created the National Diabetes Information Clearinghouse to increase knowledge and understanding about diabetes among people with these conditions and their families, health professionals, and the general public.

January 1979 – Following 2 years of study and public hearings, the National Commission on Digestive Diseases issued its report, *The National Long-Range Plan to Combat Digestive Diseases.* Recommendations to Congress included the establishment of a National Digestive Diseases Advisory Board, an information clearinghouse, and increased emphasis on educational programs in digestive diseases in medical schools.

June 1980 – The NIDDK created the National Digestive Diseases Information Clearinghouse to increase knowledge and understanding about digestive diseases among people with these conditions and their families, health professionals, and the general public.

September 1980 – Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at NIH to be named to the distinguished executive rank in the Senior Executive Service. President Jimmy Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980 – NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease," and dinner at the National Naval Medical Center. Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

June 1981 – A report entitled *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases* was prepared by an external group of scientific experts and submitted to NIH and the Senate Committee on Appropriations.

June 23, 1981 – The Institute was renamed National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

April 1982 – U.S. Department of Health and Human Services (HHS) Secretary Richard S. Schweiker elevated NIADDK's programs to division status, creating 5 extramural divisions and the Division of Intramural Research.

November 1982 – Dr. Elizabeth Neufeld received a Lasker Foundation Award. She is cited, along with Dr. Roscoe E. Brady of NINCDS, for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984 – Grants totaling more than $4 million were awarded to 6 institutions to establish Silvio O. Conte Digestive Disease Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986 – The Institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases.

June 3, 1986 – The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

1987 – The NIDDK created the National Kidney and Urologic Diseases Information Clearinghouse to increase knowledge and understanding about diseases of the kidneys and urologic system among people with these conditions and their families, health care professionals, and the general public.

August 1, 1987 – Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December 25, 1987 – In response to congressional language on the FY 1988 appropriation for the NIDDK, the institute established a program of cystic fibrosis research centers.

March, 1990 – The National Kidney and Urologic Diseases Advisory Board issued its "Long-Range Plan: Window on the 21st Century." The Plan presented recommendations for uniting the public and private sectors in the quest to prevent these diseases; improve methods for early detection, treatment, and rehabilitation; and ultimately find cures.

September 16, 1990 – NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June, 1991 – The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature.

September 30, 1992 – Three Obesity/Nutrition Research Centers and an animal models core to breed genetically obese rats for obesity and diabetes research were established.

October 12, 1992 – Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." They have received grant support from NIDDK since 1955 and 1956, respectively.

October 30, 1992 – In response to congressional language on the Institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993 – The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to NIDDK.

October 10, 1994 – Dr. Martin Rodbell and Dr. Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher in the National Institute of Arthritis and Metabolic Diseases, now NIDDK.

June 22, 1997 – Led by NIDDK, NIH and the U.S. Centers for Disease Control and Prevention (CDC) announce the National Diabetes Education Program (NDEP) at the American Diabetes Association annual meeting in Boston. The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease, and its complications.

June 2000 – In an effort to reduce the disproportionate burden of many diseases in minority populations, NIDDK initiated an Office of Minority Health Research Coordination.

July 18, 2000 – The NIDDK created the National Kidney Disease Education Program to raise awareness among the public of kidney disease and its risk factors, and make resources available to consumers and health care providers.

November 16, 2000 – NIDDK celebrated its 50th Anniversary. Professional societies in 8 U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. "A New Century of Science. A New Era of Hope" was published to highlight research supported and conducted by NIDDK and concluded the year with a joint scientific symposium at the Society for Cell Biology's 40th Anniversary meeting in December.

June 13, 2003 – To avoid confusion with the newly-established NIH Obesity Research Task Force, NIDDK changed the name of its National Task Force on Prevention and Treatment of Obesity, established in 1991, to the Clinical Obesity Research Panel (CORP).

June 2003 – The *Report on Progress and Opportunities: Special Statutory Funding for Type 1 Diabetes Research* described recent achievements and major projects that address unmet research needs in type 1 diabetes. From fiscal year 1998 through fiscal year 2008, the special funding program provides a total of $1.14 billion in research funds to supplement other funds for type 1 diabetes research provided through the regular appropriations process.

October 4, 2004 – Dr. Richard Axel, once an intramural research fellow under Dr. Gary Felsenfeld at NIDDK, shared the Nobel Prize in Physiology or Medicine with another scientist for discovering a large family of receptors selectively expressed in cells that detect specific odors.

October 6, 2004 – Long-time grantees Drs. Irwin A. Rose and Avram Hershko shared the Nobel Prize in Chemistry with another scientist for discovering ubiquitin-mediated protein degradation inside the cell.

October 8, 2003 – NIDDK grantees Dr. Peter Agre and Dr. Roderick MacKinnon shared the Nobel Prize in Chemistry for studies of channels in cell membranes. Agre discovered aquaporins, proteins that move water molecules through the cell membrane. MacKinnon received the award for his work on structural and mechanistic studies of ion channels. The two also received support from several other NIH components.

December 2004– NIDDK released *Action Plan for Liver Disease Research: A Report of the Liver Disease Subcommittee of the Digestive Diseases Interagency Coordinating Committee*. The report identifies areas of scientific opportunity leading to research goals for preventing and controlling liver and biliary diseases.

January 2005 – The trans-NIH *Action Plan for Liver Disease Research*, a comprehensive plan that addresses the burden of liver diseases in the United States and maps out challenges for future research was released. The *Action Plan* was developed under the guidance of NIDDK's Liver Disease Research Branch.

September 2005 – The NIH Director established the National Commission on Digestive Diseases to develop a long-range plan to improve the health of the Nation through digestive diseases research for submittal to the NIH Director and to Congress. NIDDK was selected as the lead agency to oversee this endeavor.

October 2006 – *Advances and Emerging Opportunities in Type 1 Diabetes Research: A Strategic Plan* developed under the leadership of NIDDK was released by NIH. The strategic plan identifies goals and objectives to exploit recent scientific advances in combating this autoimmune form of diabetes.

October 2007 – Institute grantee Dr. Oliver Smithies shared the Nobel Prize in Physiology or Medicine with two other scientists for discovering principles for introducing specific gene modifications in mice by using embryonic stem cells.

February 2008 – NIDDK developed and released the Awareness and Prevention Series of new health information to raise awareness about diabetes, digestive diseases, and kidney and urologic diseases among people not yet diagnosed with these illnesses. The fact sheets (in English or Spanish) are for use at community health fairs, workplace health forums, family reunions, and other similar events.

March 2009 – NIDDK released *Opportunities and Challenges in Digestive Diseases Research: Recommendations of the National Commission on Digestive Diseases*. The report was the culmination of a comprehensive planning process to identify research challenges and opportunities spanning the wide range of digestive conditions.

2010 – NIDDK celebrated its 60th anniversary. Special events included the September 21 scientific symposium "Unlocking the Secrets of Science: Building the Foundation for Future Advances" and the publication of the commemorative report *NIDDK: 60 Years of Advancing Research to Improve Health*.

September 2010 – NIDDK grantee Dr. Jeffrey Friedman and former grantee Dr. Douglas Coleman won the 2010 Albert Lasker Basic Medical Research Award for discovering the hormone leptin, which plays a key role in regulating energy intake and energy expenditure.

February 2011– NIDDK released *Advances and Emerging Opportunities in Diabetes Research: A Strategic Planning Report of the Diabetes Mellitus Interagency Coordinating Committee.* The report identifies opportunities for research on diabetes and its complications over the next decade.

March 2011– The NIH Obesity Research Task Force, co-chaired by NIDDK Director Dr. Griffin P. Rodgers, released the *Strategic Plan for NIH Obesity Research*. The plan recommends diverse scientific investigations to combat the obesity epidemic.

October 3, 2011 – NIDDK grantee Dr. Bruce Beutler shared the 2011 Nobel Prize in Physiology or Medicine with NIH grantee Dr. Jules Hoffman for their discoveries concerning the activation of innate immunity. NIH grantee Dr. Ralph Steinman also shared the award posthumously for his discovery of the dendritic cell and its role in adaptive immunity.

December 2011 – The journal *Science* named an HIV-prevention research study led by NIDDK grantee Dr. Myron Cohen the 2011 Breakthrough of the Year. The study found that people infected with HIV reduced the risk of transmitting the virus to their sexual partners by taking oral antiretroviral medicines when their immune systems were relatively healthy. Cohen, an NIH MERIT Award recipient, has received more than 20 years of continuous NIH funding, including NIDDK funding for basic science research earlier in his career.

NIDDK Legislative Chronology

December 11, 1947 – Under section 202 of Public Law 78-410, the Experimental Biology and Medicine Institute was established.

August 15, 1950 – P.L. 81-692, the Omnibus Medical Research Act, authorized establishment of NIAMDD to "... conduct researches relating to the cause, prevention, and methods of diagnosis and treatment of arthritis and rheumatism and other metabolic diseases, to assist and foster such researches and other activities by public and private agencies, and promote the coordination of all such researches, and to provide training in matters relating to such diseases...." Section 431 also authorized the U.S. Surgeon General to establish a national advisory council.

May 19, 1972 – President Richard M. Nixon signed P.L. 92-305 to bring renewed emphasis to research in digestive diseases by changing the name of the Institute to NIAMDD and by designating a digestive diseases committee within the Institute's National Advisory Council.

July 23, 1974 – P.L. 93-354, the National Diabetes Mellitus Research and Education Act, was signed. The National Commission on Diabetes, called for by this act, was chartered on September 17, 1974. Members were appointed by the Secretary of the U.S. Department of Health, Education and Welfare (HEW). The Act called for centers for research and training in diabetes and establishment of an intergovernmental diabetes coordinating committee, including NIAMDD and 6 other NIH institutes.

January 1975 – The National Arthritis Act of 1974 (P.L. 93-640) was signed into law to further research, education, and training in the field of the connective tissue diseases. The HEW Secretary appointed the mandated National Commission on Arthritis and Related Musculoskeletal Diseases, June 2. The Act required centers for research and training in arthritis and rheumatic diseases and the establishment of a data bank, as well as an overall plan to investigate the epidemiology, etiology, control, and prevention of these disorders.

October 1976 – P.L. 94-562, the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, established the National Diabetes Advisory Board charged with advising Congress and the HEW Secretary on implementation of the "Long-Range Plan to Combat Diabetes," developed by the National Commission on Diabetes. The law also established the National Commission on Digestive Diseases to deal with many problems, including investigation into the incidence, duration, mortality rates, and social and economic impact of digestive diseases.

December 1980 – Title II of the Health Programs Extension Act of 1980, P.L. 96-538, changed the Institute's name to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. The Act also established the National Digestive Diseases Advisory Board. The law authorized the National Diabetes Information Clearinghouse, the Diabetes Data Group, and the National Digestive Diseases Information and Education Clearinghouse. In addition, it reauthorized advisory boards for arthritis and diabetes research.

November 20, 1985 – The Health Research Extension Act of 1985, P.L. 99-158, changed the Institute name to the National Institute of Diabetes and Digestive and Kidney Diseases. The act also established

the National Kidney and Urologic Diseases Advisory Board. The law gave parallel special authorities to all Institute operating divisions, including authorization of the National Kidney and Urologic Diseases Information Clearinghouse; National Kidney, Urologic, and Hematologic Diseases Coordinating Committee; National Kidney and Urologic Diseases Data System; National Digestive Diseases Data System; Kidney and Urologic Diseases Research Centers; and Digestive Diseases Research Centers.

June 10, 1993 – The NIH Revitalization Act of 1993, P.L. 103-43, established NIDDK as the lead institute in nutritional disorders and obesity, including the formation of a research and training centers program on nutritional disorders and obesity. The Act also provided for the directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Aging, National Institute of Dental Research, and the NIDDK to expand and intensify programs with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

July 25, 1997 – A House report accompanying H.R. 2264 and Senate report with S. 1061, FY 1998 appropriations bills for the Departments of Labor, HHS, and Education, urged NIH and NIDDK to establish a diabetes research working group to develop a comprehensive plan for NIH-funded diabetes research that would recommend future initiatives and directions. The report-- *Conquering Diabetes, A Strategic Plan for the 21st Century*—was issued in 1999.

August 1997 – The Balanced Budget Act of 1997 (P.L. 105-33), as immediately amended by the Taxpayer Relief Act of 1997 (P.L. 105-34), established a *Special Statutory Funding Program for Type 1 Diabetes Research* (now Section 330B of the Public Health Service Act). This legislation provided $30 million per year for fiscal years 1998 through 2002. This funding program augmented regularly appropriated funds that HHS received for diabetes research through the Labor-HHS-Education Appropriations Committees. NIDDK, through authority granted by the HHS Secretary, has a leadership role in planning, implementing, and evaluating the allocation of these funds. In parallel with the *Special Statutory Funding Program for Type 1 Diabetes Research*, P.L. 105-33 also established the *Special Diabetes Program for Indians*, which is administered by the Indian Health Service.

October 17, 2000 – Title IV, Section 402, of the Children's Health Act of 2000 (P.L. 106-310), entitled "Reducing the Burden of Diabetes Among Children and Youth," specified that NIH conduct long-term epidemiology studies, support regional clinical research centers, and provide a national prevention effort relative to type 1 diabetes.

December 21, 2000 – The FY 2001 Consolidated Appropriations Act (P.L. 106-554) increased funding for the *Special Statutory Funding Program for Type 1 Diabetes Research* to $100 million per year for FY 2001and FY 2002 and extended the program at a level of $100 million for FY 2003.

December 17, 2002 – The Public Health Service Act Amendment for Diabetes (P.L. 107-360) extended and augmented the *Special Statutory Funding Program for Type 1 Diabetes Research* in time and amount, allocating $150 million per year for fiscal years 2004 through 2008.

December 8, 2003 – Title VII, Subtitle D, Section 733 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) authorized the NIDDK to conduct a pancreatic islet transplantation clinical trial that includes Medicare beneficiaries. Medicare would cover routine costs, transplantation, and appropriate related items and services for Medicare beneficiaries enrolled in the trial.

October 25, 2004 – The Pancreatic Islet Cell Transplantation Act of 2004(P.L. 108-362) amended the Public Health Service Act to increase the supply of pancreatic islet cells for research and provide better coordination of Federal efforts and information on islet cell transplantation. A provision of this law specified that the annual reports prepared by the NIDDK-led Diabetes Mellitus Interagency Coordinating

Committee include an assessment of the Federal activities and programs related to pancreatic islet transplantation.

September 2004 –The reports accompanying the FY 2005 Senate and House Labor, HHS, and Education appropriations bills (Senate Report 108-345 and House Report 108-636) called on NIH and HHS to establish a national commission on digestive diseases to review the burden of digestive diseases in the United States and develop a long-range research plan to address this burden. The NIH Director subsequently established the National Commission on Digestive Diseases, under NIDDK leadership, in August 2005

December 29, 2007 – The Medicare, Medicaid, and SCHIP Extension Act of 2007 (P.L. 110-173) extended funding for the *Special Statutory Funding Program for Type 1 Diabetes Research*. The law provided $150 million for type 1 diabetes research in FY 2009.

July 15, 2008 – The Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275) extended funding for the *Special Statutory Funding Program for Type 1 Diabetes Research*. The law provided $150 million per year for type 1 diabetes research in FY 2010 and FY 2011.

February 17, 2009 – President Barack Obama signed the American Recovery and Reinvestment Act (ARRA) of 2009 (P.L. 111—5), providing the NIH with a two-year infusion of funding. The NIDDK developed a plan to use its portion of the ARRA funds to meet the stimulus goals set forth in the Recovery Act. This funding supported a range of biomedical research efforts across the Institute's research mission.

June 15, 2010 – H. Res. 1444, a bipartisan resolution recognizing the 60th anniversary of the NIDDK, was introduced.

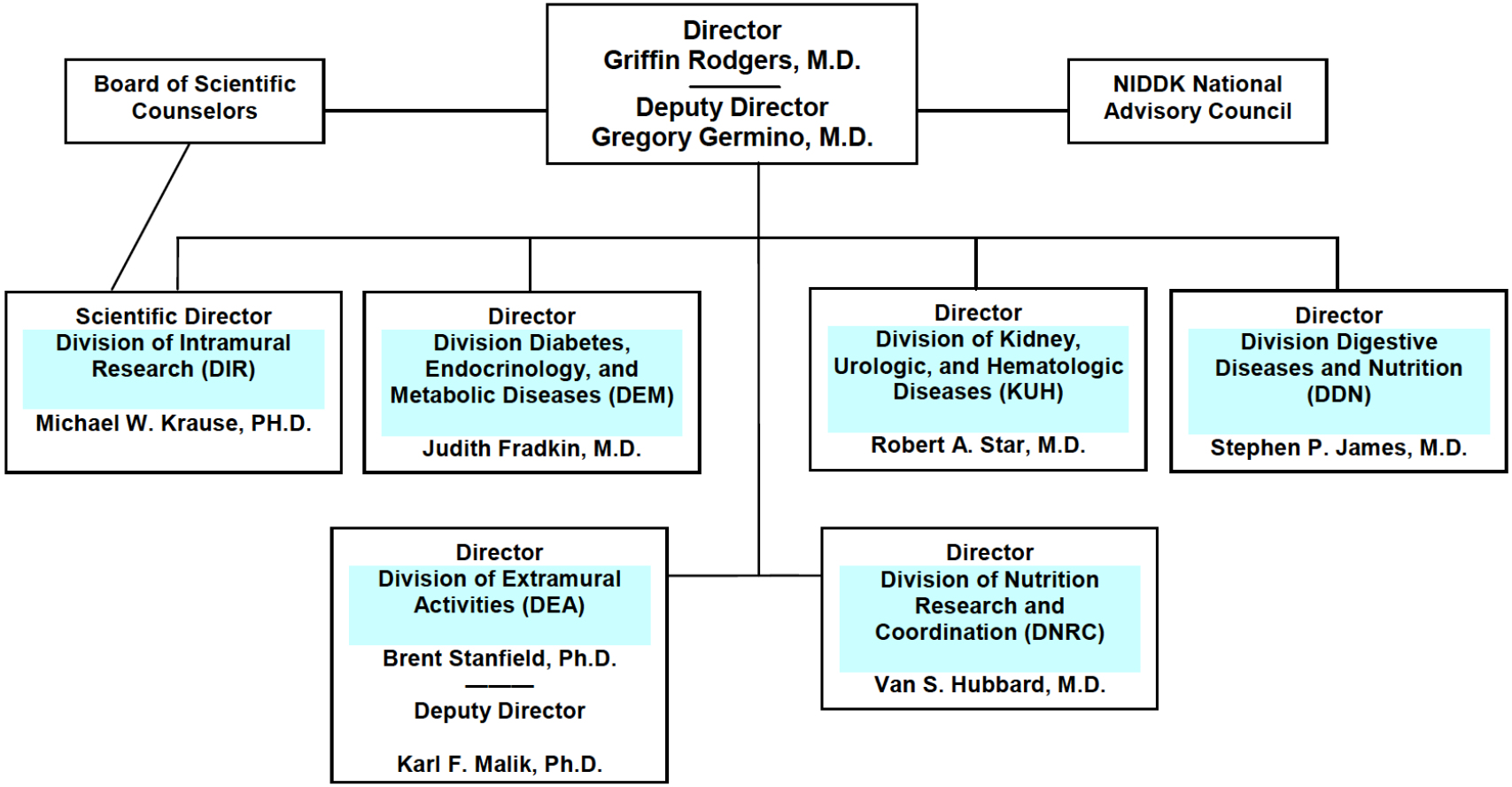
December 15, 2010 – The Medicare and Medicaid Extenders Act of 2010 (P.L. 111-309) extended funding for the *Special Statutory Funding Program for Type 1 Diabetes Research*. The law provided $150 million per year for type 1 diabetes research in FY 2012 and FY 2013.

NIDDK Directors

Name	In Office from	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999

Allen M. Spiegel	November 15, 1999	March 3, 2006
Griffin P. Rodgers	April 1, 2007	present

NIDDK Organizational Chart



Overview of the Office of the Director

In addition to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC), the Office of the Director includes the following offices:

- Executive Office, including administrative components:
  - Ethics Office
  - Office of Workforce Development and Planning (OWDP)
  - Office of Management and Policy Analysis (OMPA)
  - Office of Financial Management and Analysis (OFMA)
  - Extramural Administrative Management Branch (EAMB)
  - Intramural Administrative Management Branch (IAMB)
  - Computer Technology Branch (CTB)
  - Technology Transfer and Development Branch
- Office of Communications and Public Liaison (OCPL)
- Office of Scientific Program and Policy Analysis (OSPPA)

Also within the Office of the Director are the following two research coordination offices.

The NIDDK director created the ***Office of Minority Health Research Coordination*** *(OMHRC)* to address the burden of diseases and disorders that disproportionately impact the health of minority populations. The OMHRC will help implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Center on Minority Health and Health Disparities at NIH.

The NIDDK ***Office of Obesity Research*** (OBR) is responsible for coordination of obesity-related research within NIDDK, and carries out its functions through the NIDDK Obesity Research Working Group. The Office is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch, the Office of Scientific Program and Policy Analysis (OSPPA), and the Division of Nutrition Research Coordination (DNRC). The responsibilities of the NIDDK Obesity Research Working Group are: (1) to provide a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities; (2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; (3) to identify and plan appropriate workshops and conferences; and (4) to assist in the preparation of obesity-related reports and inquiries.

Under the auspices of the NIDDK Advisory Council, the National Task Force on Prevention and Treatment of Obesity was established in June 1991. In June 2003, the name was changed to the *Clinical Obesity Research Panel (CORP)*. The mission of the CORP is to synthesize current scientifically based information on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature. It is composed of leading obesity researchers and clinicians who advise the institute on research needs and sponsor workshops on topics related to the prevention and treatment of obesity. The CORP serves in an advisory capacity to the Weight-control Information Network (WIN).

Biographical Sketch of NIDDK Director Griffin P. Rodgers, M.D., M.A.C.P.

Dr. Griffin P. Rodgers was named Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)—one of the National Institutes of Health (NIH)—on April 1, 2007. He had served as NIDDK's Acting Director since March 2006 and had been the Institute's Deputy Director since January 2001. Dr. Rodgers provides scientific leadership and manages a staff of more than 600 employees and a budget of $2.0 billion.

Dr. Rodgers received his undergraduate, graduate, and medical degrees from Brown University in Providence, R.I. He performed his residency and chief residency in internal medicine at Barnes Hospital and the Washington University School of Medicine in St. Louis. His fellowship training in hematology was in a joint program of the NIH with George Washington University and the Washington Veterans Administration Medical Center. In addition to his medical and research training, he earned a master's degree in business administration, with a focus on the business of medicine and science, from Johns Hopkins University in 2005.

As a research investigator, Dr. Rodgers is widely recognized for his contributions to the development of the first effective—and now FDA approved—therapy for sickle cell anemia. He was a principal investigator in clinical trials to develop therapy for patients with sickle cell disease. He also performed basic research that focused on understanding the molecular basis of how certain drugs induce gamma-globin gene expression. In 2009, he and his collaborators reported on a modified blood stem-cell transplant regimen that is highly effective in reversing sickle cell disease in adults and is associated with relatively low toxicity, for which he was elected to the 2912 class of the National Academy of Sciences. He has also been honored for his research with numerous awards including the 1998 Richard and Hinda Rosenthal Foundation Award, the 2000 Arthur S. Fleming Award, the Legacy of Leadership Award in 2002, and a Mastership from the American College of Physicians in 2005.

Dr. Rodgers has been an invited professor at medical schools and hospitals in France, Italy, China, Japan, and Korea. He has been honored with many named lectureships at American medical centers; has published over 200 original research articles, reviews, and book chapters; has edited 4 books and monographs; and holds 3 patents.

Dr. Rodgers is a member of the American Society of Hematology, the American Society of Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academy of Sciences, among others. He served as Governor to the American College of Physicians and as chair of the Hematology Subspecialty Board and as a member of the American Board of Internal Medicine Board of Directors. He is board certified in Internal Medicine, in Emergency Medicine, and in Hematology.

How To Contact Us

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Deputy Director	Dr. Gregory G. Germino	Building 31, 9A52	(301) 496-5877 germinogg@mail.nih.gov

Executive Office (NIDDK EO) (includes Ethics Office contacts)

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Deputy Executive Officer	Lisa Mascone	Building 31, 9A48	(301) 496-5765 masconel@niddk.nih.gov
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EEO Specialist	Alfreda Layne	2115 E. Jefferson St. Rm. BE64	(301) 435-6260 laynea@mail.nih.gov
Deputy Ethics Counselor	Traci Melvin	Building 31, 9A16	(301) 827-4225 melvint@mail.nih.gov
Director, Technology Transfer & Development Branch	Cindy Fuchs	Building 12A, 3011	(301) 451-3636 cfuchs@mail.nih.gov

Office of Workforce Development and Planning (NIDDK OWDP)

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Workforce Resources Specialist	Linda Mongelli	Building 31, 9A27	(301) 594-7772 lindam@mail.nih.gov
Workforce Resources Specialist	Andrea Brush	Building 31, 9A27	(301) 594-7772 brusha@mail.nih.gov

Office of Management and Policy Analysis (NIDDK OMPA)

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Office of Financial Management and Analysis (NIDDK OFMA)

Position	Name	Location	Phone No./Email
Budget Officer	Van Nguyen	Building 31, 9A34	(301) 594-4722 vnguye1@mail.nih.gov
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Extramural Administrative Management Branch (NIDDK EAMB)

Position	Name	Location	Phone No./Email
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Intramural Administrative Management Branch (NIDDK IAMB)

Position	Name	Location	Phone No./Email
Chief Administrative Officer	Randy Redmond	Building 10, 9N208	(301) 496-5100 redmonra@mail.nih.gov

Computer Technology Branch (NIDDK CTB)

Position	Name	Location	Phone No./Email
Chief Information Officer	Cyrus Karimian	2 Democracy Plaza, Rm. 930	(301) 496-9555 karimianc@mail.nih.gov
Deputy Chief Information Officer	Max Niakani	2 Democracy Plaza, Rm. 940	(301) 594-7762 niakanim@mail.nih.gov

Office of Communications and Public Liaison (NIDDK OCPL)

Position	Name	Location	Phone No./Email
Director	Kathy Kranzfelder	Building 31, 9A06	(301) 496-3583 KranzfelderK@mail.nih.gov
Press Officer	Mary Harris	Building 31, 9A06	(301) 496-3583 harrismm@mail.nih.gov

Office of Scientific Program and Policy Analysis (NIDDK OSPPA)

Position	Name	Location	Phone No./Email
Director	Dr. Richard Farishian	Building 31, 9A05	(301) 496-6623 farishianr@hq.niddk.nih.gov
Deputy Director	Dr. Lisa Gansheroff	Building 31, 9A05	(301) 496-6623 gansheroffl@mail.nih.gov

Office of Minority Health Research Coordination (OMHRC)

Position	Name	Location	Phone No./Email
Director	Dr. Lawrence Agodoa	2 Democracy Plaza, Rm. 902	(301) 594-1932 agodoal@extra.niddk.nih.gov

Office of Obesity Research (OOR)

Position	Name	Location	Phone No./Email
Co-Director	Dr. Phil Smith	2 Democracy Plaza, Rm. 693	(301) 594-8816 psmith@extra.niddk.nih.gov
Co-Director	Dr. Sue Yanovski	2 Democracy Plaza, Rm. 665	(301) 594-8882 yanovskis@extra.niddk.nih.gov

Overview of the Division of Intramural Research

The Division of Intramural Research oversees research and training conducted within the NIDDK's laboratories and clinical facilities by government scientists in Bethesda, MD, and Phoenix, AZ. Several of NIDDK's intramural scientists have received national and international awards for scientific excellence.

The division includes 10 branches, nine laboratories, and four offices, which focus on issues of technology transfer, fellow recruitment and career development, and the overall management of the division's basic and clinical research efforts. In addition, nine core facilities provide centralized scientific support services to the laboratories and branches.

The intramural branches conduct basic, translational, and clinical biomedical research related to diabetes mellitus, endocrine, bone and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; kidney diseases; and hematologic diseases. The NIDDK's intramural labs are involved in fundamental research in biophysics; cell biology; chemical biology and medicinal chemistry; developmental biology; genetics, pathogenesis, and novel therapies of disease; molecular biology; signal transduction; and structural biology

Website: http://www2.niddk.nih.gov/NIDDKLabs/NIDDKLabsAbout.htm

How To Contact Us

Division of Intramural Research (DIR)

Position	Name	Location	Phone No./Email
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Clinical Director	James E. Balow, M.D.	Bldg. 10-CRC, Rm. 5-2551	(301) 496-4181 jimb@mail.nih.gov
Director, Fellowship Office	Louis Simchowitz, M.D., MBA	Bldg. 12A, Rm. 3011	(301) 451-3640 ls347@nih.gov

Overview of the Division of Extramural Activities

The Division of Extramural Activities (DEA) provides leadership, oversight, tools, and guidance to manage the NIDDK's grants policies and operations, including efforts related to the scientific peer review process for assessing grant applications. The DEA also coordinates the NIDDK's committee management activities and Advisory Council meetings, and performs and coordinates programmatic analysis and evaluation activities.

The DEA is organized into three primary components:

- the Grants Management Branch, the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NIDDK
- the Scientific Review Branch, which coordinates the initial scientific peer review of applications submitted in response to Request for Applications (RFAs), training and career awards, program projects, multi-center clinical trials, and research contracts, including Loan Repayment Program applications. Most R01s, fellowship, and SBIR grant applications are reviewed in the Center for Scientific Review.
- the Office of Research Evaluation and Operations (OREO), within the DEA Office of the Director, oversees and coordinates disease coding/reporting for the NIDDK extramural program, manages the Early Notification System and NIH Guide publication process associated with publishing Funding Opportunity Announcements, and supports NIDDK Advisory Council activities. The office also facilitates harmonization of activities among NIDDK's four extramural divisions, and coordinates/performs special projects at the request of the NIDDK leadership.

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/DEA/

How To Contact Us

Division of Extramural Activities (DEA)

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Deputy Director	Dr. Karl F. Malik	2 Democracy Plaza, Rm. 718	(301) 594-4757 km89r@nih.gov

Position	Name	Location	Phone No./Email
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OREO	Christine Salaita	2 Democracy Plaza, Rm. 716	(301) 443-9908 csalaita@niddk.nih.gov

Committee Management Office

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Position	**Name**	**Location**	**Phone No./Email**
Committee Management Officer	Devon Drew	2 Democracy Plaza, Rm. 616A	(301) 402-9332 devond@extra.niddk.nih.gov

Review Branch

Building	U.S. Postal Address		UPS, Fedex, etc.
2 Democracy Plaza	6707 Democracy Blvd., Rm. 767, MSC 5452, Bethesda, MD 20892-5452		6707 Democracy Blvd., Rm. 752, Bethesda, MD 20817
Position	**Name**	**Location**	**Phone No./Email**
Chief	Dr. Francisco Calvo	2 Democracy Plaza, Rm.752	(301) 594-8897 calvof@extra.niddk.nih.gov
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Chartered Review Committees Section 2 Chief	Dr. John Connaughton	2 Democracy Plaza, Rm. 753	(301) 594-7797 connaughtonj@extra.niddk.nih.gov
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Scientific Review Administrator	Dr. Maria Davila-Bloom	2 Democracy Plaza, Rm. 758	(301) 594-7637 davila- bloomm@extra.niddk.nih.gov

Position	Name	Location	Phone No./Email
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Scientific Review Administrator	Dr. Xiaodu Guo	2 Democracy Plaza, Rm. 910	(301) 496-4724 guox@niddk.nih.gov
Scientific Review Administrator	Dr. Ann Jerkins	2 Democracy Plaza, Rm. 759	(301) 594-2242 jerkinsa@mail.nih.gov
Scientific Review Administrator	Dr. D.G. Patel	2 Democracy Plaza, Rm. 914	(301) 594-7682 pateldg@extra.niddk.nih.gov
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Grants Management Branch

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Position	**Name**	**Location**	**Phone No./Email**
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Supervisory Grants Management Specialist	Vacant	2 Democracy Plaza, Rm. 710	
Supervisory Grants Management Specialist	Mary K. Rosenberg	2 Democracy Plaza, Rm. 745	(301) 594-8891 RosenbergM@mail.nih.gov
Supervisory Grants Management Specialist	Marilyn Rosendorf	2 Democracy Plaza, Rm. 723	(301) 402-4625 rosendorfm@mail.nih.gov

Overview of the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM)

The Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM) supports research, research training, and career development related to a vast and diverse range of diseases and conditions, including diabetes mellitus, obesity, osteoporosis, cystic fibrosis, thyroid and other endocrine disorders, and metabolic diseases. The division also leads the administration of trans-NIH diabetes research; coordinates federally supported, diabetes-related activities; promotes public awareness and education about diabetes and other diseases; and collects and disseminates data.

Diabetes Research Programs

The division encompasses 25 diabetes research programs, including the

- Adipocyte Biology Research Program
- Autoimmunity/Viral Etiology of Type 1 Diabetes Research Program
- Behavioral/Prevention Research Program
- Beta Cell Therapy Research Program
- Clinical Islet Transplantation Consortium Program
- Clinical Research in Type 2 Diabetes Program
- Complications of Diabetes Research Program
- Developmental Biology Research Program
- Diabetes Centers Program
- Drug Discovery Program
- Endocrine Pancreas Research Program
- Environmental Determinants of Diabetes in the Young (TEDDY)
- Genetics of Type 1 Diabetes Research Program
- Genetics of Type 2 Diabetes Research Program
- Glucose Sensors Research Program
- Hypoglycemia in Diabetes Research Program
- Insulin Receptor/Structure/Function/Action Research Program
- Islet Transplantation Research Program
- Molecular and Functional Imaging Program
- Mouse Metabolic Phenotyping Program
- Pharmacogenetics and Personalized Medicine in the Treatment of Diabetes
- Prevention of Type 1 Diabetes Research Program
- Type 1 Diabetes Clinical Trials Program
- Type 2 Diabetes Clinical Trials Program
- Type 2 Diabetes in the Pediatric Population Research Program

Endocrinology Research Programs

The division encompasses seven endocrinology research programs, including the

- Bone and Mineral Metabolism Research Program
- G-Protein Coupled Receptors Program
- Integrative Biology of Obesity Program
- Intracellular Signal Transduction Research Program

- Neuroendocrinology Research Program
- Nuclear Receptor Superfamily Program
- Regulation of Energy Balance and Body Composition Research Program

Metabolic Diseases Research Programs

The division encompasses 13 metabolic diseases research programs, including the

- Cystic Fibrosis Research Program
- Functional Metabolomics Program
- Gene Therapy and Cystic Fibrosis Centers Program
- Gene Therapy Research Program
- Genomic Resource and Technology Development Program
- Inborn Errors of Metabolism Research Program
- Integrative Metabolism and Insulin Resistance Program
- Intrauterine Environment
- Key Regulators of Intermediary Metabolism
- Metabolic Imprinting
- Metabolomics Technology Development Roadmap Program
- Protein Trafficking/Secretion/Processing Research Program
- Proteomics in Diabetes, Endocrinology, and Metabolic Diseases Program

Diabetes Mellitus Interagency Coordinating Committee

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) coordinates diabetes research and activities across the NIH and other federal programs. The division director chairs the DMICC, which includes representatives from all federal departments and agencies whose programs involve health functions and responsibilities relevant to diabetes and its complications.

National Diabetes Data Group

The DEM's National Diabetes Data Group serves as the federal lead for collecting, analyzing, and sharing data on diabetes and its complications. The group draws on the expertise of the research, medical, and lay communities to support its data initiatives.

National Diabetes Education Program
See "Health Information and Education Services."

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/ddemd_table/.htm

How To Contact Us

Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM)

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NIH Building 31	31 Center Dr., Rm. 9A-16, MSC 2510,Bethesda, MD 20892-2510		31 Center Dr., Rm. 9A-16,Bethesda, MD 20892
Position	**Name**	**Location**	**Phone No./Email**
Director	Dr. Judith Fradkin	Bldg 31. Rm. 9A27	(301) 496-7349 fradkinj@mail.nih.gov
Deputy Director; Co-Director, Office of Obesity Research	Dr. Philip Smith	2 Democracy Plaza, Rm. 689	(301) 594-8816 smithp@mail.nih.gov
Program Director, Cell Signaling and Diabetes Centers	Dr. Kristin M. Abraham	2 Democracy Plaza, Rm. 607	(301) 451-8048 abrahamk@mail.nih.gov
Immunopathogenesis and Genetics of Type 1 Diabetes Program Director	Dr. Beena Akolkar	2 Democracy Plaza, Rm. 6105	(301) 594-8812 akolkarb@mail.nih.gov
Director, Islet Biology and Transplantation Research Program	Dr. Michael C. Appel	2 Democracy Plaza, Rm. 792	(301) 594-4740 appelm@mail.nih.gov
Director, Clinical Immunology, Type 1 Diabetes Program	Dr. Guillermo A. Arreaza-Rubin	2 Democracy Plaza, Rm. 6101	(301) 594-4724 arreaza-rubing@mail.nih.gov
Director, Endocrine Systems Biology Program	Dr. Olivier Blondel	2 Democracy Plaza, Rm. 796	(301) 451-7334 blondelol@mail.nih.gov
Director, Metabolomics and Informatics Programs	Dr. Arthur L. Castle	2 Democracy Plaza, Rm. 791	(301) 594-7719 castlea@mail.nih.gov
Director, Diabetes Epidemiology Program	Dr. Catherine Cowie	2 Democracy Plaza, Rm. 691	(301) 594-8804 cowiec@mail.nih.gov
Director, Islet Transplantation Clinical Trials Program	Dr. Thomas L. Eggerman	2 Democracy Plaza, Rm. 697	(301) 594-8813 eggermant@mail.nih.gov
Senior Advisor for Biometry and Behavioral Research Program	Dr. Sanford Garfield	2 Democracy Plaza, Rm. 685	(301) 594-8803 garfields@mail.nih.gov

Position	Name	Location	Phone No./Email
Senior Advisor for Cell Biology Associate Director for Grants Administration	Dr. Carol Renfrew Haft	2 Democracy Plaza, Rm. 793	(301) 594-7689 haftc@mail.nih.gov
Director, Behavioral Research Program	Dr. Christine Hunter	2 Democracy Plaza, Rm. 675	(301) 594-4728 hunterchristine@niddk.nih.gov
Senior Advisor for Research Training and Career Development	Dr. James Hyde	2 Democracy Plaza, Rm. 603	(301) 435-8116 hydej@mail.nih.gov
Diabetes Complications Program Director	Dr. Teresa Jones	2 Democracy Plaza, Rm. 609	(301) 435-2996 jonester@mail.nih.gov
Metabolism and Structural Biology Program Director	Dr. Maren Laughlin	2 Democracy Plaza, Rm. 6101	(301) 594-8802 laughlinm@mail.nih.gov
Type 1 Diabetes Trialnet Program Director	Dr. Ellen Leschek	2 Democracy Plaza, Rm. 603	(301) 402-8291 ellenl@mail.nih.gov
Senior Advisor for Childhood Diabetes Research	Dr. Barbara Linder	2 Democracy Plaza, Rm. 699	(301) 594-0021 linderb@mail.nih.gov
Senior Advisor for Endocrine Physiology	Dr. Saul Malozowski	2 Democracy Plaza, Rm. 607	(301) 451-4683 sm87j@mail.nih.gov
Senior Advisor, Molecular Endocrinology and Associate Director for Grants Administration	Dr. Ronald Margolis	2 Democracy Plaza, Rm. 693	(301) 594-8819 margolisr@mail.nih.gov
Senior Advisor for Genetic Research	Dr. Catherine McKeon	2 Democracy Plaza, Rm. 6103	(301) 594-8810 mckeonc@mail.nih.gov
Director, Neurobiology of Obesity and Developmental Biology	Dr. Sheryl Sato	2 Democracy Plaza, Rm. 790	(301) 594-8811 smsato@mail.nih.gov
Senior Advisor, Clinical Diabetes Research	Dr. Peter Savage	2 Democracy Plaza, Rm. 788A	(301) 594-8858 savagep@niddk.nih.gov
Proteomic Program Director	Dr. Salvatore Sechi	2 Democracy Plaza, Rm. 611	(301) 594-8814 ss24q@mail.nih.gov
Director, Intracellular and Intrauterine Signaling Programs	Dr. Corinne Silva	2 Democracy Plaza, Rm. 794	(301) 451-7335 silvacm@niddk.nih.gov

Position	Name	Location	Phone No./Email
Director, Immunobiology of Type 1 Diabetes Program and Autoimmune Endocrine Diseases Program	Dr. Lisa Spain	2 Democracy Plaza, Rm. 695	(301) 451-9871 spainl@mail.nih.gov
Senior Advisor, Diabetes Research Translation	Dr. Myrlene Staten	2 Democracy Plaza, Rm. 6107	(301) 402-7886 statenm@mail.nih.gov

Overview of the Division of Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition (DDN) supports research related to digestive diseases, including the alimentary tract, liver and pancreas, nutrition and obesity. The programs include basic, translational and clinical research. DDN also promotes public awareness and education about digestive diseases and related conditions, and oversees several national public awareness campaigns.

Digestive Diseases Research Programs

Alimentary tract programs

- Basic Neurogastroenterology
- Clinical Trials in Digestive Diseases
- Gastrointestinal and Nutrition AIDS
- Gastrointestinal Development
- Gastrointestinal Epithelial Biology
- Gastrointestinal Host-microbial Interactions
- Gastrointestinal Inflammation
- Gastrointestinal Motility
- Gastrointestinal Mucosal Inflammation and Immunology
- Gastrointestinal Transport and Absorption
- Gastroparesis Consortium
- Genetics and Genomics of the Gastrointestinal Tract and its Diseases

Liver Disease Research Programs

- Acute Liver Failure
- Autoimmune Liver Disease
- Bile, Bilirubin and Cholestasis
- Bioengineering and Biotechnology
- Cell and Molecular Biology of the Liver
- Childhood Liver Disease Network
- Clinical Trials in Liver Disease
- Complications of Chronic Liver Disease
- Developmental Biology and Regeneration
- Drug-induced Liver Disease
- Fatty Liver Disease
- Gallbladder Disease and Biliary Diseases
- Genetic Liver Disease
- Genetics and Genomics of Liver/Pancreas Diseases
- Hepatitis B
- HIV and Liver
- Liver Cancer
- Liver Cell Injury, Repair, Fibrosis and Inflammation
- Liver Transplantation
- Nonacoholic Steatohepatitis Network

- Pediatric Acute Liver Failure
- Pediatric Liver Disease
- Viral Hepatitis and Infectious Diseases

Pancreas Research Programs

- Gastrointestinal Neuroendocrinology
- Pancreas Research
- Study of Nutrition in Acute Pancreatitis

Obesity Research Programs

- Bariatric Surgery Clinical Research Consortium
- Clinical Obesity and Nutrition
- Genetics and Genomics of Obesity
- Lifestyle Interventions in Obese Pregnant Women
- Lifestyle Interventions in Pregnancy Consortium
- Obesity and Eating Disorders
- Obesity Prevention and Treatment
- Pediatric Clinical Obesity
- Study of Health Outcomes of Weight-loss

Nutrition Sciences Research Programs

- Clinical Obesity and Nutrition
- Clinical Trials in Nutrition
- Genetics and Genomics of Nutrition
- Nutritional Epidemiology and Data Systems
- Nutrient Metabolism

Cross-cutting programs

- Career Development
- Digestive Diseases Epidemiology and Data Systems
- Digestive Diseases Centers
- Individual Research Fellowship
- Loan Repayment
- Nutrition Obesity Research Centers
- Small Business
- T32 Training

The division oversees the following health education and awareness campaigns:

- Celiac Disease Awareness Campaign
- Ways to Enhance Children's Activity and Nutrition (We Can!)
- Weight-control Information Network
- Bowel Control Awareness Campaign

For more information about these initiatives, see "Health Information and Education Services."

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/dnrc_table/.htm

How To Contact Us

Division of Digestive Diseases and Nutrition (DDN)

Building	**U.S. Postal Address**		**UPS, Fedex, etc.**
2 Democracy Plaza	6707 Democracy Blvd., Rm. 654, MSC 5450 Bethesda, MD 20892-5450 (301) 594-2323		6707 Democracy Blvd., Rm. 601, Bethesda, MD 20817
NIH Building 31	31 Center Dr., Rm. 9A27, MSC 2560, Bethesda, MD 20892-2560		31 Center Dr. Rm. 9A27, Bethesda, MD 20892
Position	**Name**	**Location**	**Phone No./Email**
Director	Dr. Stephen James	2 Democracy Plaza, Rm. 677	(301) 594-7680 Jamess@extra.niddk.nih.gov
Deputy Director	Dr. Jay Hoofnagle	Building 31, Rm. 9A27	(301) 496-1333 hoofnaglej@extra.niddk.nih.gov
Program Analyst	Ms. Lauren Meskill	2 Democracy Plaza, Rm. 677	(301) 402-7503 meskillL@extra.niddk.nih.gov

Epidemiology and Clinical Trials Branch

Position	**Name**	**Location**	**Phone No./Email**
Branch Chief; Director; Epidemiology and Data Systems Program Project Officer; Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) Clinical Trial	Dr. James (Jay) Everhart	2 Democracy Plaza, Rm. 655	(301) 594-8878 everhartj@extra.niddk.nih.gov
Clinical Trials Specialist	Ms. Rebecca J. Torrance	2 Democracy Plaza, Rm. 646	(301) 594-7024 torrancer@niddk.nih.gov

Digestive Diseases Branch

Position	**Name**	**Location**	**Phone No./Email**
Branch Chief; Director; Gastrointestinal Motility Program Director; Gastrointestinal Mucosa and	Dr. Frank Hamilton	2 Democracy Plaza, Rm. 669	(301) 594-8877 hamiltonf@extra.niddk.nih.gov

Immunology Program Director; AIDS Program			
Director; Pancreas Program	Dr. Jose Serrano	2 Democracy Plaza, Rm. 657	(301) 594-8871 serranoj@extra.niddk.nih.gov
Director; Gastrointestinal Transport and Absorption Program	Dr. Michael J. Grey	2 Democracy Plaza, Rm. 665	(301) 451-3759 greym@mail.nih.gov
Director; Digestive Diseases Centers Program; Director; Training and Career Development Program	Dr. Judith Podskalny	2 Democracy Plaza, Rm. 667	(301) 594-8876 podskalnyj@extra.niddk.nih.gov
Director; Genetics and Genomics in Digestive Diseases and Obesity Programs	Dr. Robert Karp	2 Democracy Plaza, Rm. 671	(301) 451-8875 karpr@extra.niddk.nih.gov
Director; SBIR/STTR Training Program	Ms. Christine Densmore	2 Democracy Plaza, Rm. 649	(301) 402-8714 DensmoreC@extra.niddk.nih.gov
Director; Gastrointestinal Development and Epithelial Biology and Inflammation Program; Director; Basic Neuro-gastroenterology	Dr. Jill Carrington	2 Democracy Plaza, Rm. 788A	(301) 402-0671 carringj@mail.nih.gov
Director; Special Projects in Nutrition, Obesity, and Digestive Diseases	Dr. Mary Evans	2 Democracy Plaza, Rm. 681	(301) 594-4578 evansmary@mail.nih.gov
Program Director, Gastrointestinal transport and Absorption	Dr. Michael J. Grey	2 Democracy Plaza, Rm. 665	(301) 451-3759 greym@mail.nih.gov

Nutritional Sciences Branch

Position	Name	Location	Phone No./Email
Branch Chief; Director, Obesity and Eating Disorders Program	Dr. Susan Yanovski	2 Democracy Plaza, Rm. 675	(301) 594-8882 yanovskis@extra.niddk.nih.gov
U.S.-Japan Nutrition and Metabolism Panel	Dr. Robert Kuczmarski	2 Democracy Plaza, Rm. 673	(301) 451-8354 kuczmarskir@extra.niddk.nih.gov
Director; Training and	Dr. Judith Podskalny	2 Democracy	(301) 594-8876

Career Development Program		Plaza, Rm. 667	podskalnyj@extra.niddk.nih.gov
Director; Obesity Special Projects Program; Director; Look AHEAD Program	Dr. Mary Evans	2 Democracy Plaza, Rm. 681	(301) 594-4578 evansmary@mail.nih.gov
Director; Obesity Prevention and Treatment Program	Dr. Robert Kuczmarski	2 Democracy Plaza, Rm. 673	(301) 451-8354 KuczmarskiR@extra.niddk.nih.gov
Director; SBIR/STTR Training Program	Ms. Christine Densmore	2 Democracy Plaza, Rm. 649	(301) 402-8714 DensmoreC@extra.niddk.nih.gov
Director; Pediatric Clinical Obesity Program	Dr. Mary Horlick	2 Democracy Plaza, Rm. 679	(301) 594-4726 horlickm@niddk.nih.gov
Director, Special Projects in Nutrition, Obesity, and Digestive Diseases	Dr. Mary Evans	2 Democracy Plaza, Rm. 681	(301) 594-4578 evansmary@mail.nih.gov
Director, Nutrition and Clinical Obesity Program	Dr. Padma Maruvada	2 Democracy Plaza, Rm. 663	(301) 594-8884 padma_maruvada@nih.gov

Liver Diseases Research Branch

Position	**Name**	**Location**	**Phone No./Email**
Branch Chief	Dr. Jay H. Hoofnagle	Bldg 31, Rm. 9A27	(301) 96-1333 Hoofnaglej@extra.niddk.nih.gov
Director; Liver and Biliary Diseases Program	Dr. Jose Serrano	2 Democracy Plaza, Rm. 657	(301) 594-8871 Serranoj@extra.niddk.nih.gov
Director; Liver Diseases Research Program	Dr. Edward Doo	2 Democracy Plaza, Rm. 651	(301) 451-4524 dooe@niddk.nih.gov
Director; SBIR/STTR Training Program	Ms. Christine Densmore	2 Democracy Plaza, Rm. 649	(301) 402-8714 DensmoreC@extra.niddk.nih.gov
Position	**Name**	**Location**	**Phone No./Email**
Director; Training and Career Development Program	Dr. Judith Podskalny	2 Democracy Plaza, Rm. 667	(301) 594-8876 podskalnyj@extra.niddk.nih.gov
Scientific Advisor, Viral Hepatitis and Liver Diseases	Dr. Averell H. Sherker	2 Democracy Plaza, Rm. 642F	(301) 594-8876 averell.sherkerj@nih.gov

Overview of the Division of Kidney, Urologic, and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic (KUH) Diseases provides research funding and support for basic, translational, and clinical research studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. The division also provides funding for training and career development of people committed to academic and clinical research in these areas.

Kidney Diseases Research Programs

The division encompasses research programs related to kidney research, including

- Acute Kidney Injury
- Basic Kidney Biology
- Chronic Kidney Disease
- Developmental Biology of the Kidney
- Diabetic Kidney Disease
- End-Stage Renal Disease
- Genetics and Genomics
- Inflammatory Kidney Disease
- Kidney HIV/AIDS
- Pediatric Kidney Disease
- Polycystic Kidney Disease
- Renal Diseases Epidemiology
- U.S. Renal Data System (USRDS)

Urological Diseases Research Programs

The division encompasses research programs related to urology research, including

- Basic Cell Biology of the Bladder and Prostate
- Basic Urology Clinical Urology
- Developmental Biology of the Urogenital Tract
- Genetics and Genomics of Urology
- Pediatric Urology
- Urologic Diseases Epidemiology
- Urology Basic Science
- Urology Clinical Science
- Urology HIV/AIDS
- Urology Technology Development
- Urology Women's Health Studies
- Urologic Diseases in America Epidemiology Program

Hematology Research Programs

The division encompasses research programs related to hematology research, including the

- Basic and Translational Hematology Research
- Erythropoiesis and Hemoglobin
- Genetic and Genomic Hematology Research
- Hematology HIV/AIDS
- Hematopoiesis and Hematopoietic Stem Cell Biology
- Heme-Net program
- Iron and Heme Metabolism, Iron Chelation
- Stimulating Hematology Investigation: New Endeavors (SHINE) program

The division oversees the following health education and awareness campaigns:

- Bladder Control for Women
- National Kidney Disease Education Program

For more information about these initiatives, see "Health Information and Education Services."

Website: http://www2.niddk.nih.gov/AboutNIDDK/Organization/kuh_table/.htm

How To Contact Us

Division of Kidney, Urologic, and Hematologic Diseases

Building	**U.S. Postal Address**		**UPS, Fedex, etc.**
2 Democracy Plaza	6707 Democracy Blvd., Rm. 654, MSC 5458, Bethesda, MD 20892-5458		6707 Democracy Blvd., Rm. 601, Bethesda, MD 20817
NIH Building 31	31 Center Dr., Rm. 9A-17, MSC 2510, Bethesda, MD 20892-2510		31 Center Dr., Rm. 9A-17, Bethesda, MD 20892
Position	**Name**	**Location**	**Phone No./Email**
Director. KUH	Dr. Robert Star	Bldg 31, Rm 9A-19 and 2 Democracy Plaza, Rm. 625	(301) 496-6325 and (301) 594-7717 starr@extra.niddk.nih.gov
Deputy Director, KUH Basic Science, Program Director, Kidney Basic Physiology	Dr. Chris J. Ketchum	2 Democracy Plaza, Rm. 647	(301) 594-7717 KetchumC@extra.niddk.nih.gov
Deputy Director, KUH Clinical Science, Program Director, Pediatric Nephrology and Urology; Kidney Centers; Kidney Small Business	Dr. Marva Moxey-Mims	2 Democracy Plaza, Rm. 639	(301) 594-7717 moxey-mimsm@extra.niddk.nih.gov

Position	Name	Location	Phone No./Email
Director; Office of Minority Health Research Coordination	Dr. Lawrence Agodoa	2 Democracy Plaza, Rm. 611 and Rm. 653	(301) 594-7717 and (301) 594-9650 agodoal@extra.niddk.nih.gov
Program Director, Women's Urologic Health	Dr. Tamara Bavendam	2 Democracy Plaza, Rm. 615	(301) 594-7717 and (301) 594-4733 Tamara.bavendam@nih.gov
Program Director, Hematology Basic Research; Hematology Centers; Hematology Training and Careers	Dr. Terry Rogers Bishop	2 Democracy Plaza, Rm. 619	(301) 594-7717 bishopt@extra.niddk.nih.gov
Program Director, Epidemiology and U.S. Renal Data System; End-Stage Renal Disease	Dr. Paul Eggers	2 Democracy Plaza, Rm. 615	(301) 594-7717 eggersp@extra.niddk.nih.gov
Program Director, Clinial Chronic Kidney Disease; Inflammatory Kidney Disease; Clinical PKD; PKD Centers	Dr. Michael Flessner	2 Democracy Plaza, Rm. 641	(301) 594-7717 flessnermf@mail.nih.gov
Program Director, Kidney and Uro-genital Development; Kidney and Urology Regeneration and Repair; Urology Centers	Dr. Deborah Hoshizaki	2 Democracy Plaza, Rm. 645	(301) 594-7712 hoshizakid@niddk.nih.gov
Program Director, Clinical Acute Kidney Injury; Kidney Translational Genetics; Kidney HIV/AIDS	Dr. Paul Kimmel	2 Democracy Plaza, Rm. 612	(301) 594-7717 KimmelP@extra.niddk.nih.gov
Program Director, Clinical and Trans-lational Research in Urologic Diseases	Dr. Ziya Kirkali	2 Democracy Plaza, Rm. 627	(301) 594-7717 KirkaliZ@niddk.nih.gov
Program Director, Kidney and Urology Trials	Dr. John Kusek	2 Democracy Plaza, Rm. 617	(301) 594-7717 kusekj@extra.niddk.nih.gov

Position	Name	Location	Phone No./Email
Program Director, Urology Basic Cell Biology; Urology Small Business	Dr. Christopher Mullins	2 Democracy Plaza, Rm. 637	(301) 594-7717 mullinsc@extra.niddk.nih.gov
Director, National Kidney Disease Education Program; Program Director, Kidney Education and Translation	Dr. Andrew Narva	2 Democracy Plaza, Rm. 645	(301) 594-8864 narvaa@extra.niddk.nih.gov
Program Director, Kidney and Urology Training and Career Development; Diabetic Uropathy; Erectile Dysfunction; Urology Molecular Endocrinology; Urology HIV/AIDS	Dr. Tracy Rankin	2 Democracy Plaza, Rm. 623	(301) 594-7717 rankint@mail.nih.gov
Program Director, Genetics and Genomics; Basic PKD	Dr. Rebekah Rasooly	2 Democracy Plaza, Rm. 643	(301) 594-7717 Rasoolyr@extra.niddk.nih.gov
Program Director, Basic Acute Kidney Injury; Basic Chronic Kidney Disease	Dr. Krystyna Rys-Sikora	2 Democracy Plaza, Rm. 612	(301) 594-7717 ryssikok@mail.nih.gov
Program Director,Hematology Basic Research; Hematology Small Business	Dr. Daniel Wright	2 Democracy Plaza, Rm. 621	(301) 594-7714 wrightdan@niddk.nih.gov

Overview of the Division of Nutrition Research Coordination

The Division of Nutrition Research Coordination (DNRC) advises the National Institutes of Health (NIH) Director and others on nutrition research issues and works with the NIH organizational components to coordinate nutrition research and research training initiatives. Since the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the lead institute for nutrition research at NIH, this NIH-wide division is located within NIDDK.

DNRC also represents NIH and provides liaison at DHHS and interagency level on various committees on nutrition research and policy issues such as the Interagency Committee on Human Nutrition Research and Nutrition Policy Board. Located within the DNRC is the NIH Nutrition Coordinating Committee (NCC) which operates as an NIH-wide forum to review, stimulate, and encourage the support of nutrition research and training to better define the role of nutrition in the promotion and maintenance of health and in the prevention and treatment of disease. The NCC also plays a key role in the development of nutrition research policy at the NIH. Further, the DNRC maintains the Human Nutrition Research Information Management (HNRIM) system. HNRIM is a searchable database of nutrition research and research training activities supported by the federal government. Data for the system is prepared and submitted by participating agencies, and is updated annually.

Website: http://dnrc.nih.gov/

How To Contact Us

Division of Nutrition Research Coordination (DNRC)

Building	**U.S. Postal Address**		**UPS, Fedex, etc.**
2 Democracy Plaza	6707 Democracy Blvd., Rm. 679, MSC 5461, Bethesda, MD 20892-5450		6707 Democracy Blvd., Rm. 679, Bethesda, MD 20817 (301) 594-8822
Position	**Name**	**Location**	**Phone No./Email**
Director	Dr. Van S. Hubbard	2 Democracy Plaza, Rm. 631 DNRC	(301) 594-8883 and 594-8827 Van_Hubbard@nih.gov
Deputy Director	Dr. Pamela Starke-Reed	2 Democracy Plaza, Rm. 633 DNRC	(301) 594-8805 Pamela_Stark-Reed@nih.gov
Nutrition Program Analyst	Rachel Fisher	2 Democracy Plaza, Rm. 628 DNRC	(301) 594-7722 fisherrachel@mail.nih.gov
Senior Public Health and Science Policy Advisor	Sheila Fleischhacker	2 Democracy Plaza, Rm. 635 DNRC	(301) 594-7440 Sheila.fleischhacker@nih.gov

Position	Name	Location	Phone No./Email
HNRIM Coordinator	Jim Krebs-Smith	2 Democracy Plaza, Rm. 626 DNRC	(301) 594-8823 James_Krebs-Smith@nih.gov
Health Program Specialist	Crystal McDade-Ngutter	2 Democracy Plaza, Rm. 636 DNRC	(301) 451-2064 mcdade-ngutterc@mail.nih.gov
Nutrition Education Coordination/Nutritionist	Margaret McDowell	2 Democracy Plaza, Rm. 629 DNRC	(301) 594-8824 mcdowellma@mail.nih.gov
Nutritionist	Karen S. Regan	2 Democracy Plaza, Rm. 640 DNRC	(301)-435-6199 Karen_Regan@nih.gov
Program Specialist	Yvonne Chow	2 Democracy Plaza, Rm. 624A DNRC	(301) 594-8821 Yvonne.chow@nih.hhs.gov
Secretary	Sharon Frazier	2 Democracy Plaza, Rm. 624C DNRC	(301) 594-8822 fraziers@niddk.nih.gov

Funding Mechanisms (Activity Codes) Supported by NIDDK

Brief Overview

An Activity Code is a three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). General categories include:

- F – fellowships
- K – career development awards
- N – research contracts
- P – program project and research center grants
- R – research project grants
- S – research-related programs
- T – training grants
- U – cooperative agreements
- Y – interagency agreements

Extramural research activities are divided into three main mechanisms: grants, cooperative agreements, and contracts. A mechanism is the type of funding instrument used at the NIH. In general, with grants (all activity codes other than "N" or "U"), investigators are responsible for developing the concepts, methods, and approach for a research project. With contracts ("N" series), the DHHS awarding unit is responsible for establishing the detailed requirements. With cooperative agreements ("U" series), both the awarding unit and the recipient have substantial responsibility. Programs are areas within the funding mechanisms (for example, research, training, fellowships, and cooperative agreements). Activity codes identify categories applied to various mechanisms.

For NIH-wide activity codes and definitions beyond the NIDDK codes listed below, go to Types of Grant Programs page (http://grants.nih.gov/grants/funding/funding_program.htm) to search activity codes or to the comprehensive list of extramural grant and cooperative agreement activity codes for more information on selected grant programs.

Special NIH-Wide Programs

DP1 **NIH Director's Pioneer Award** (NDPA) (Roadmap program)
To support individuals who have the potential to make extraordinary contributions to medical research. The NDPA is not renewable.

DP2 **NIH Director's New Innovator Awards** (Roadmap program)
To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

DP3 **Type 1 Diabetes Targeted Research Award**
To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

Fellowship Programs

F 31 **Predoctoral Individual National Research Service Award**
To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

F 32 **Postdoctoral Individual National Research Service Award**
To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

F 33 **National Research Service Awards for Senior Fellows**
To provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

Research Career Programs

K 01 **Research Scientist Development Award - Research & Training**
For support of a scientist, committed to research, in need of both advanced research training and additional experience.

K 08 **Clinical Investigator Award (CIA)**
To provide the opportunity for promising medical scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research aspects of categorical areas applicable to the awarding unit, and aid in filling the academic faculty gap in these shortage areas within health profession's institutions of the country.

K 12 **Physician Scientist Award (Program) (PSA)**
For support to a newly trained clinician appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

K 18 **The Career Enhancement Award**
To provide either full-time or part-time support for experienced scientists who wish to broaden their scientific capabilities or to make changes in their research careers by acquiring new research skills or knowledge. Career enhancement experiences supported by this award should usually last no more than one year.

K 22 **Career Transition Award**
To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial period involving and intramural appointment at the NIH and a final period of support at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator in order to sustain or promote a successful research career.

K 23 **Mentored Patient-Oriented Research Career Development Award**
To provide support for the career development of investigators who have made a commitment of focus their research endeavors on patient-oriented research. This mechanism provides support for a 3 year minimum up to 5 year period of supervised study and research for

clinically trained professionals who have the potential to develop into productive, clinical investigators.

K 24 **Midcareer Investigator Award in Patient-Oriented Research**
To provide support for the clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators.

K 25 **Mentored Quantitative Research Career Development Award**
To engender and foster such activities by supporting the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have made a commitment to focus their research endeavors on behavioral and biomedical research (basic or clinical). This mechanism is aimed at research-oriented scientists with experience at the level of junior faculty (e.g., early to mid-levels of assistant professor or research assistant professor ranks). This award provides support for a period of mentored study and research for professionals with such backgrounds who have the potential to integrate their expertise with biomedicine and develop into productive investigators.

Examples of quantitative scientific and technical backgrounds outside of biology or medicine considered appropriate for this award include, but are not limited to: mathematics, statistics, computer science, informatics, physics, chemistry, and engineering.

K 30 **Clinical Research Curriculum Award (CRCA)**
The CRCA is an award to institutions and is intended to stimulate the inclusion of high-quality, multi-disciplinary didactic training as part of the career development of clinical investigators. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research to support or expand their programs or to improve the quality of instruction.

K 99 **NIH Pathway to Independence Award (PI)**
R 00 To provide an opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. The primary purpose of the Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The initial phase (K99 Career Transition Award) provides 1-2 years of mentored support for highly motivated, advanced postdoctoral research scientists. The second phase (R00 Research Transition Award) provides 1-3 years of independent research support contingent on securing an independent research position. Award recipients will be expected to compete successfully for independent R01 support from the NIH during the R00 research transition award period.

KM1 **Institutional Career Enhancement Awards - Multi-Yr Funding**
Provides for part-time (minimum 25% effort) up to full-time support for medical, scientific, statistics and health care professionals with post-doctoral or equivalent experience selected by an institution, to broaden their research capabilities by acquiring new research skills or knowledge. Further it provides for curriculum development of new programs to support these same types of individuals. This is an institutional mentored career program, not an individual program. It is also a multi-year funded institutional mentored career development activity thus ICs need OER prior approval to use the KM1.

Extramural Loan Repayment Program

L 30 **Loan Repayment Program for Clinical Researchers**
To provide for the repayment of the educational loan debt of qualified health professionals involved in clinical research. Qualified health professionals who contractually agree to conduct qualified clinical research are eligible to apply for this program.

L 40 **Loan Repayment Program for Pediatric Research**
To provide for the repayment of the educational loan debt of qualified health professionals involved in research directly related to diseases, disorders, and other conditions in children.

Qualified health professionals who contractually agree to conduct qualified pediatric research are eligible to apply for this program.

Research and Development-Related Contracts

N 01 **Research and Development Contracts**
To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

N 02 **Resource and Support Contracts - Awarded in the ICD**
To support intramural and extramural station support needs. This activity also includes the provision of resources to intramural research programs.

N 41 **Small Business Technology Transfer (STTR) Contracts - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

N 42 **Small Business Technology Transfer (STTR) Contracts - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

N 43 **Small Business Innovation Research (SBIR) Contracts- Phase I**
To support project, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s). These contracts may be made only with small businesses.

N 44 **Small Business Innovation Research (SBIR) Contracts - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be made only to small businesses.

Research Program Projects and Centers

P 01 **Research Program Projects**
For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the

organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project

is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P 20 **Exploratory Grants**

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P 30 **Center Core Grants**

To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant is integrated with the center's component projects or program projects, though funded independently from them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects.

P 50 **Specialized Center**

To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

P 60 **Comprehensive Center**

To support a multipurpose unit designed to bring together into a common focus divergent but related facilities within a given community. It may be based in a university or may involve other locally available resources, such as hospitals, computer facilities, regional centers, and primate colonies. It may include specialized centers, program projects and projects as integral components. Regardless of the facilities available to a program, it usually includes the following objectives: to foster biomedical research and development at both the fundamental and clinical levels; to initiate and expand community education, screening, and counseling programs; and to educate medical and allied health professionals concerning the problems of diagnosis and treatment of a specific disease.

Research Projects

R 01 **Research Project**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R 03 **Small Research Grants**
To provide research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies which are generally for preliminary short-term projects and are non-renewable.

R 13 **Conference**
To support recipient sponsored and directed international, national or regional meetings, conferences and workshops.

R 15 **Academic Research Enhancement Awards (AREA)**

To support small scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to $75,000 for direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R 18 **Research Demonstration and Dissemination Projects**
To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R 21 **Exploratory/Developmental Grants**
To encourage the development of new research activities in categorical program areas. (Support generally is restricted in level of support and in time.)

R 24 **Resource-Related Research Projects**
To support research projects that will enhance the capability of resources to serve biomedical research.

R 25 **Education Projects**
For support to develop and/or implement a program as it relates to a category in one or more of the areas of education, information, training, technical assistance, coordination, or evaluation.

R 33 **Exploratory/Developmental Grants Phase II**
The R33 award is to provide a second phase for the support for innovative exploratory and development research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under R33.

R 34 **Clinical Trial Planning Grant**
To provide support for the initial development of a clinical trial, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

R 37 **Method to Extend Research in Time (MERIT) Award**
To provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT award. Program staff and/or members of the cognizant National Advisory Council/Board will identify candidates for the MERIT award during the course of review of competing research grant applications prepared and submitted in accordance with regular PHS requirements.

R 41 **Small Business Technology Transfer (STTR) Grants - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R 42 **Small Business Technology Transfer (STTR) Grants - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

R 43 **Small Business Innovation Research (SBIR) Grants - Phase I**
To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

R 44 **Small Business Innovation Research (SBIR) Grants - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. SBIR Phase II are considered ˜Fast-Track˜ and do not require National Council Review.

R 56 **High Priority, Short Term Project Award**
To provide limited interim research support based on the merit of a pending R01 application while applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Interim funded ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

RC1 **NIH Challenge Grants and Partnerships Program**
As part of the American Recovery and Reinvestment Act of 2009 (Recovery Act), NIH designated at least $200 million in FYs 2009 - 2010 for this new initiative to fund 200 or more grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. The new program will support research that addresses specific scientific and health research challenges in biomedical and behavioral research that will benefit from significant 2-year jumpstart funds. In addition, Recovery Act funds allocated to NIH specifically for comparative effectiveness research (CER) may be available to support additional grants.

RC2 **High Impact Research and Research Infrastructure Programs**
To support high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and

investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/ resource designed to accelerate scientific progress in the future.

RC3 **Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Program**
To accelerate the transition of NIH-supported research innovations and technologies toward the development of products or services that will improve human health, through grants that may advance the mission of NIH and its Institutes and Centers (ICs), and create significant value and economic stimulus or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code is intended to support research and development (R&D) specifically targeted at activities that can help address the funding gap between promising R&D and transitioning to the market, often called the "Valley of Death" by contributing the critical funding needed by applicants to pursue the next appropriate milestone(s) toward ultimate commercialization; i.e., to carry out later stage research activities necessary to that end; to foster partnerships among a variety of research and development (R&D) collaborators working toward these aims. Awards are made only to U.S.-owned, for-profit enterprises doing a majority of its business in the United States. RC3 applications may be given funding priority if the applicant organization is associated with an enterprise that is of small size (e.g., 500 or fewer employees), and/or of limited resources, such as an early-stage company, and/or one positioned for receiving funding or in-kind support from a third-party investor and/or strategic partner. The RC3 SPAN program is not intended to support "upstream" R&D for doing feasibility testing of an innovative idea or to conduct early-stage R&D as an extension of such ideas. (Projects such as these should be submitted under the NIH SBIR/STTR programs.)

RC4 **High Impact Research and Research Infrastructure Programs—Multi-Yr Funding**
To support multi-year funded research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the multi-year funded companion activity code to the existing RC2; thus ICs need OER prior approval to use the RC4.

Research-Related Programs

S 06 **Minority Biomedical Research Support - MBRS**
To strengthen the biomedical research and research training capability of ethnic minority institutions, and thus establish a more favorable milieu for increasing the involvement of minority faculty and students in biomedical research.

SC 1 **Research Enhancement Award**
Individual investigator-imitated research projects aimed at developing researchers at minority-serving institutions (MSIs) to a stage where they can transition successfully to other s extramural support (R01 or equivalent).

SC 2 **Pilot Research Project**

Individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for a more ambitious research project.

SC 3 **Research Continuance Award**
Individual investigator-initiated research projects for faculty at MSIs to conduct research of limited scope in environments with limited research infrastructure/facilities.

Training Programs

T 32 **Institutional National Research Service Award**
To enable institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas.

T 35 **NRSA Short-Term Research Training**
To provide individuals with research training during off-quarters or summer periods to encourage research careers and/or research in areas of national need.

T90 **Interdisciplinary Research Training Award**
To support comprehensive interdisciplinary research training programs at the undergraduate, predoctoral and/or postdoctoral levels, by capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs.

Cooperative Agreements

Note: For all funding mechanisms within this section, substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

U 01 **Research Project--Cooperative Agreements**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U 10 **Cooperative Clinical Research--Cooperative Agreements**
To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and are usually conducted under established protocols.

U 13 **Conference--Cooperative Agreements**
To support international, national or regional meetings, conferences and workshops where substantial programmatic involvement is planned to assist the recipient.

U 19 **Research Program--Cooperative Agreements**
To support a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach. This generally involves the organized efforts of large groups, members of which are conducting research projects designed to elucidate the various aspects of a specific objective. Each project supported through this mechanism should contribute to or be directly related to the common theme of the total research effort. The award can provide support for certain basic shared resources, including clinical components, which facilitate the total research effort. These

scientifically meritorious projects should demonstrate an essential element of unity and interdependence.

U 24 **Resource-Related Research Projects--Cooperative Agreements**
To support research projects contributing to improvement of the capability of resources to serve biomedical research.

U-32 **State-Based Diabetes Control Programs**
Programs in cooperation with State health agencies: To reduce the effect of preventable problems in service delivery to diabetics (such as excess days of hospitalization, high amputation rates, and the effect of insurance policy on securing care), to define the preventable service delivery problems, and to demonstrate improved service delivery to diabetics.

U 34 **Multi-Center Clinical Study Implementation Planning Grants**
Clinical Planning Grant Cooperative Agreement—To provide support, substantial Federal programmatic involvement, and technical assistance for the initial development of a clinical trial. Also, it would include the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

UC4 **High-Impact Research and Research Infrastructure Cooperative Agreements**
To support multi-year funded cooperataive agreement research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the cooperative agreement companion to the RCA. It is also the multi-year funded companion to the existing UC2; thus ICs need OER prior approval to use the UC 4.

UH3 **Exploratory/Developmental Cooperative Agreement Phase II**
To provide a second phase for the support for innovative exploratory and development research activities initiated under the UH2 mechanism. Although only UH2 awardees are generally eligible to apply for UH3 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under UH2.

UM- **Multi-Component Research Project Cooperative Agreements**
To support large-scale cooperative agreements involving complex clinical trials with multiple components (e.g., clinical networks). The components represent a variety of supporting functions and are not independent of the research projects. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award. The performance period may extend up to 7 years but only through the established deviation request process. ICs desiring to use this activity code for programs greater than 5 years must receive OPERA prior approval through the deviation request process.

X01 **Resource Access Program**

To invite eligible institutions to seek access to NIH research resources. This includes programs where institutions will request access to submit to the resource, e.g., high throughput screening assays. It also includes programs where access to a specific NIH research resource is needed to conduct certain research.

NIH Fiscal Policy for Grant Awards – FY 2013

NIH Operates Under a Continuing Resolution - UPDATE

Notice Number: **NOT-OD-13-018**

Key Dates

Release Date: January 2, 2013

Related Announcements

NOT-OD-13-002

Issued by

National Institutes of Health (NIH)

Purpose

NIH continues to operate under a Continuing Resolution as described in NOT-OD-13-002 until further notice.

NIH Operates Under a Continuing Resolution

Notice Number: **NOT-OD-13-002**

Update: The following update relating to this announcement has been issued:

- January 2, 2013 - See Notice NOT-OD-13-018. NIH Operates Under a Continuing Resolution - UPDATE.

Key Dates

Release Date: October 11, 2012

Issued by

National Institutes of Health (NIH)

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under a Continuing Resolution (CR) (H. J. Resolution 117) that was signed by President Obama as Public Law 112-175 on September 28, 2012. The CR continues government operations through March 27, 2013 at the FY 2012 level plus 0.6 percent.

Until FY 2013 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006 - 2012. Upward adjustments to awarded levels will be considered after our FY 2013 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2012 remain in effect under the CR, including the salary limitation set at Executive Level II of the Federal Pay Scale ($179,700), which was effective with grant awards with an initial Issue Date on or after December 23, 2011 (see NOT-OD-12-034 and NOT-OD-12-035).

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

NIH Fiscal Policy for Grant Awards – FY 2012 [example]

Notice Number: NOT-OD-12-036

Key Dates

Release Date: January 20, 2012

Issued by

National Institutes of Health (NIH)

Purpose

This Notice provides guidance about the NIH Fiscal Operations Plan for FY 2012 and implements the Consolidated Appropriations Act of 2012 (P.L. 112-74), signed by President Obama on December 23, 2011. The Act provides NIH with $30.7 billion, an increase of less than one percent over FY 2011 (after transfers). The NIH will continue to manage its portfolio in biomedical research investments in a manner that includes addressing the need for a highly productive pool of researchers by providing support for new investigators.

The following NIH fiscal policies are instituted in FY 2012:

FY2012 Funding Levels: Non-competing awards will be issued without cost of living/inflationary adjustments in FY 2012; however adjustments for special needs (such as equipment and added personnel) will continue to be accommodated. This policy applies to all grants (research and non-research) when applicable.

The NIH will make efforts to keep the average size of awards constant at FY 2011 levels or lower. For new and competing grants, NIH awarding Institutes/Centers (IC) will develop funding principles consistent with overall NIH goals, considering the funds provided to their IC this fiscal year.

Inflationary Increases for Future Years: Inflationary increases for future year commitments will be discontinued for all competing and non-competing research grant awards issued in FY 2012, however adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.

FY 2012 awards that have already been issued will be revised to adjust the award level and future year commitments in accordance with these principles.

Ruth L. Kirschstein National Research Service Awards (NRSA): The NIH will implement a two percent increase at all stipend levels. Further information about NRSA stipends in FY 2012 will be published in the NIH Guide in the near future

New Investigators: NIH will continue to support new investigators on R01 equivalent awards at success rates equivalent to that of established investigators submitting new (Type 1) R01 equivalent applications. Achievement of comparable success rates should permit the NIH to support new investigators in accordance with the policies established in FY 2009 and subsequent years and described at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html and at http://grants.nih.gov/grants/new_investigators/index.htm.

Salary Limits: Section 203 of the Consolidated Appropriations Act prohibits payments for salaries under grants and other extramural mechanisms to rates in excess of Executive Level II. Guidance related to Section 203 will be published in the NIH Guide in the near future.

Additional Information: Additional details on Fiscal Operations, including specific funding strategies for ICs will be posted at http://grants.nih.gov/grants/financial/index.htm.

Inquiries

Questions about specific awards may be directed to the Grants Management Specialist identified in the Notice of Award.

For related Notices see Notice of Legislative Mandates in Effect for FY2012 (NOT-OD-12-034) National Institutes of Health; Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts (NOT-OD-12-035) National Institutes of Health; and Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2012 (NOT-OD-12-033)

NIDDK FY 2013 Interim Funding Policy

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and clinical research on many of the most serious diseases affecting public health.

NIDDK extramural research is organized into 3 programmatic divisions: 1) Diabetes, Endocrinology, and Metabolic Diseases; 2) Digestive Diseases and Nutrition; and 3) Kidney, Urologic, and Hematologic Diseases.

The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, cooperative agreements, career development and training awards, and contracts.

The Department of Health and Human Services (HHS), including NIH is presently operating under a Continuing Resolution that continues government operations through March 27, 2013.

- Until FY 2013 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). See NOT-OD-13-002 for details (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-002.html).
- NIDDK will announce additional details regarding its interim FY 2013 funding policy, including details regarding funding of competing grant applications, once an NIH-wide policy has been announced.

NIDDK FY 2012 Interim Funding Policy [example]

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and clinical research on many of the most serious diseases affecting public health.

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The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, cooperative agreements, career development and training awards, and contracts.

Budget Data

Current Appropriation

NIDDK's appropriation for fiscal year 2012 is $1.797 billion. This is an increase of 0.3% from NIDDK's appropriation in fiscal year 2011.

Funding Strategy

NIDDK is committed to supporting as many meritorious competing research grant applications as possible. Consistent with NIH policy (see NIH Guide Notice NOT-OD-12-036), NIDDK will manage its portfolio in biomedical research investments in a manner that includes addressing the need for a highly productive pool of researchers by providing support for investigators who are at an early stage in their careers.

To maximize our available resources and to comply with NIH policy requiring that NIH Institutes and Centers strive to keep the average size of awards constant at FY 2011 levels or lower, all grant awards will continue to be subject to programmatic adjustments from the National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council approved levels. These adjustments take into consideration the overall scientific and technical merit of the grant application, the cost of the proposed research, and other resources available for related research projects.

Funding Guidelines

Competing Awards

For FY 2012 NIDDK is establishing a nominal "payline" for new (Type 1) and renewal or competing continuation (Type 2) R01 applications of 13th percentile. Most R01 applications which have a primary assignment to NIDDK and which request less than $500,000 direct cost per year and score at or better than the 13th percentile will receive an award (applications which have NIDDK as a secondary assignment do not benefit from this payline). R01 applications requesting $500,000 or more in direct costs for any year will be held to a more stringent pay line – the 8th percentile for both Type 1 and 2 applications. It should be noted that NIDDK will exercise discretion and consider

portfolio balance, programmatic importance and a number of other factors in determining precisely which applications are awarded. In addition, all grant awards will continue to be subject to programmatic adjustments from the NDDK Advisory Council approved levels. It is important to note that these funding levels are applicable for applications to be paid in FY 2012. Most applications submitted in FY 2012 (e.g., those submitted in January for September/October council consideration) will not be eligible for funding consideration until FY 2013. The funding levels for FY 2013 cannot now be reliably predicted.

Early Stage Investigators (ESIs)

Fostering the success of investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH. In FY 2012 NIDDK will place special emphasis on supporting ESIs (investigators within 10-years of their terminal research degree or medical residency who have not yet been awarded a substantial, competing NIH research grant; see ESI FAQs) by establishing a nominal payline for R01 applications submitted by ESIs at the 18th percentile. In addition, when possible and appropriate the full period of support recommended will be awarded.

Bridge Support

In cases where a competing renewal application falls near but beyond the nominal payline, NIDDK will continue to consider interim support on a case-by-case basis and provide limited, support in selected cases. The goal is to preserve essential research resources pending the re-review of a revised application. NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These awards provide support for investigators to collect preliminary data and use these data to revise and improve their R01 applications.

Duration of Grant Support

Competing awards are adjusted to achieve a 4.4 year average duration for research project grants. Nevertheless, applications from ESIs, initial MERIT awards, MERIT extensions, program project grants, and clinical trial grants are generally awarded for the full length of their recommended project period.

Salaries

Salaries on all grants are limited to $179,700 with issue dates on/after December 23, 2011 (see NOT-OD-12-035 - Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts). For grants with issue dates on/before December 22, 2011 the salary limitation is $199,700 for the FY2012 award period. Future years of all grants will be adjusted to reflect the $179,700 limit. Non-competing grants may re-budget any funds freed as a result of the lower cap.

Inflationary Increases for Future Years

Per the NIH Fiscal Policy for Grant Awards - FY2012 (NOT-OD-12-036), inflationary increases for future year commitments will be discontinued for all competing and non-competing research grant awards issued in FY 2012, however adjustments for special needs (such as equipment and added personnel) will continue to be accommodated.

Non-competing (Continuation) Awards

As required by the NIH Fiscal Policy for Grant Awards - FY2012 (NOT-OD-12-036) non-competing (Type 5) awards will be issued without cost of living/inflationary adjustments in FY 2012; however adjustments for special needs (such as equipment and added personnel) will continue to be accommodated. This policy applies to all grants (research and non-research) when applicable.

Program Project (P01) Grant Applications and Applications with budgets greater than $500K

NIDDK has adopted a more stringent funding practice for awarding program project (P01) grants, Collaborative Interdisciplinary Team Science (R24) and other investigator-initiated grant applications with budgets of $500,000 requested direct costs in any one year. Prior approval is required before submitting an application for review that requests $500,000 or more in direct costs in any one year. The request to submit such applications should be received at least three months prior to the proposed submission date. Prior approval is required for renewal and revised applications as well as new applications. Please consult with the appropriate NIDDK program staff and visit the following site for information on research areas supported by NIDDK:
http://www2.niddk.nih.gov/Research/ScientificAreas/.

New (Type 1) program project (P01) applications may request a maximum of $6.25 million in direct costs over five years, exclusive of the subcontract Facilities & Administrative (F&A) costs. Renewal (competing continuation [Type 2]) program project applications may request up to $6.25 million in direct costs over five years, exclusive of Facilities and Administrative (F&A) costs associated with the subcontract(s). In addition to the caps on the amount requested, P01 awards are subject to administrative adjustment from the Advisory Council approved levels. Also, any P01 grant receiving a competing award in FY 2011 or later will be limited to one subsequent renewal. Additional information regarding the P01 applications and their receipt dates can be found:
http://www2.niddk.nih.gov/Funding/Grants/GrantReview/P01Guidelines.htm.

Resources for New NIDDK Investigators

New investigators represent the future. They bring fresh ideas and technologies to research. NIDDK is dedicated to providing training and research funding for new investigators working on topics within its mission.

NIH Opportunities

NIH has policies and resources designed to assist new investigators in establishing their research programs and careers. New investigators should check the "New PI" box on the face page of their R01 applications so that they can be given special consideration. Peer reviewers are instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator. Institute staff pay special attention to applications from new investigators as well. In addition, NIH has piloted a program for rapid turnaround for new investigator applications allowing them to revise and resubmit more quickly.

NIDDK Opportunities

NIDDK has created a number of special new investigator opportunities and Frequently Asked Questions for new investigators. You are encouraged to discuss your ideas with NIDDK program staff as you are planning and preparing your grant application. Check NIDDK scientific areas of interest to find the right staff members and their contact information.

Differential payline – Each year, the NIDDK sets a percentile "payline" for R01 applications based on available funds and the volume of applications. The payline for new investigator grants is two percentile points more generous than the regular payline for established investigators. While NIDDK often makes administrative reductions in grant duration, applications from new investigators that fall within the payline are usually awarded the full requested duration.

Second-level review – The NIDDK Advisory Council meets to provide second-level review after the initial round of peer review by Scientific Review Groups (study sections). All new investigator R01 applications within ten percentile points of the payline receive individual consideration during the second-level review process. This could result in the award of an R01 with a reduced budget or a smaller award such as an R56.

NIH High Priority, Short-Term Project Award (R56) – Although you cannot apply for this grant mechanism, NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect preliminary data in order to submit an improved revised R01 application. During second-level review, new investigators are given special consideration for R56 awards.

Career Development (K) awards – NIDDK has a vigorous Career Award program.

Small grants (R03) awards – NIDDK has several relevant funding opportunities for small grants.

Mentoring workshops – NIDDK regularly holds workshops for recently funded new investigators.

Website: NIDDK has a webpage specifically to assist New Investigators:
http://www2.niddk.nih.gov/Funding/Grants/Resources_NewInvestigators.htm

Role of NIDDK Advisory Council

Established by law and charter, the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meets three times annually to advise the NIDDK about its research portfolio. The Council typically undertakes broad issues of science policy. An important role of the Council is to provide second-level peer review of grant applications that have been scored by scientific review groups. The Council members are an important liaison between the research communities they represent and NIDDK, which supports each community's research efforts.

Who are the Council members?

Members of the Advisory Council are drawn from the scientific and lay communities, are appointed for 4-year terms, and represent all areas within the Institute's research mission. The Council membership consists of 18 voting members, including 12 health or science experts and 6 public members.

Six nonvoting, *ex officio* members provide liaison with higher level agencies or organizations having missions consistent with that of NIDDK, including the Secretary, Department of Health and Human Services (DHHS), and representatives from the Department of Defense, Centers for Disease Control and Prevention, and Department of Veterans' Affairs.

Council's health or science experts contribute technical expertise and an understanding of the needs of the research communities of academia and industry. Council's public representatives impart a perspective of people affected by diseases in NIDDK's research mission.

Each Council member also belongs to one of the three Council subcommittees – Digestive Diseases and Nutrition; Diabetes, Endocrinology, and Metabolic Diseases; and, Kidney, Urologic and Hematologic Diseases, corresponding to NIDDK's extramural programmatic divisions.

A copy of the current Council roster is included in the next section on Advisory Council Logistical documents and online at http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/AdvisoryCouncilRoster.htm.

What does the Council do?

As required by law, chartered advisory committees, including the councils, are part of every NIH institute. NIDDK's Council performs the following four key roles:

- Conducts second-level peer review of grant applications scored by scientific review groups
- Advises NIDDK on broad issues of science policy
- Reviews NIDDK programs
- Clears concepts for Program Announcements (PAs), Requests for Applications (RFAs), and Requests for Proposals (RFPs).

The subcommittees conduct most of the NIDDK Division-specific other business, including the closed-session discussion of grant applications.

What is second-level review?

Second-level review is the assessment of the quality of the initial review of grant applications. The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application

for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote.

Expedited Concurrence of En Bloc Actions. For grant and cooperative agreement applications that have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), excluding those from foreign organizations, a process of expedited concurrence is available. The purpose is to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive, and responsible manner. In this process, the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee consists of the Council Executive Secretary and six members of the NDDKAC. Two members are selected from each subcommittee of the NDDKAC. Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within 7 days of notification of posting is required for expedited concurrence approval.

For the first two Councils – January or February and May or June – expedited review enables NIDDK to fund grants a few weeks after the initial peer review meeting. Because September Council reviews applications for funding in the next fiscal year, applicants approved for funding through expedited review will get their awards after the Institute receives its next year's appropriation.

The NIDDK Director makes final funding decisions based on staff and Advisory Council/Board advice.

What happens at Council meetings?

Council meets in September, January or February, and May or June. Its activities are driven partly by the budget and appropriation cycle. For example, discussions in September reflect the beginning of the fiscal year.

In the morning, the full Council meets in open session to hear updates from the Director, NIDDK, and to discuss items that cut across NIDDK Divisional lines. This may include scientific and administrative topics for discussion, often presented by staff or outside speakers.

In the early afternoon, the three subcommittees meet individually to review applications needing special consideration, discuss selective pay nominations, and recommend MERIT awards. Then, the Director, NIDDK, convenes the full Council for a short, closed meeting to discuss and formally approve subcommittee recommendations for funding grants.

Note: A sample agenda is included in the on Advisory Council Logistical documents. The next meeting's agenda is posted several weeks before each meeting and is available from the Council's home page (http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/). Minutes are also posted and available from the home page.

What is Council's role in concept clearance?

NIDDK seeks Council's advice for long-term planning at an early stage. However, the decision to go forward with an initiative is made by NIDDK, based on scientific and programmatic priorities and on the availability of funds.

Definitions of Special Issues Presented to Council

Program staff must prepare the following types of special issues to present to Council.

1. **Reinstatement of Research Aims**. Applications for which the division is requesting to reinstate specific aims or research not recommended for support by the study section.

2. **Non-Peer-Reviewed Applications**. Used in some circumstances. Council performs both initial peer review and second-level review functions. Renewal MERIT awards are the most common example.

3. **Deferred Applications**. All Council-deferred applications independent of review results.

4. **Unresolved Appeals.** Formerly called rebuttals. When program staff working with a scientific review officer have been unable to resolve the applicant's concerns, the DEA director reviews the appeal, and staff present it to Council.

5. **Foreign Applications**. Foreign applications a division proposes to award. (Foreign applicants may NOT receive R56-Bridge awards.)

6. **Council Member Applications**. Applications proposed for award where a Council member is PI. A subcommittee other than the one on which the Council member serves reviews these applications.

7. **Human Subjects**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of human subjects.

8. **Biohazards**. Applications proposed for award with unresolved concerns about biohazards.

9. **Use of Animals in Research**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of animals in research.

10. **Minority Recruitment Plans in Institutional Training Grant Applications**. Fundable, meritorious National Research Service Award applications with inadequate plans for minority recruitment. When the study section deems a plan inadequate, options are (1) no special action, pay by priority score; (2) defer payment pending submission and staff approval of a recruitment plan; or (3) defer for study section re-review pending receipt of an acceptable plan.

11. **Inclusion of Women and Minorities as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

12. **Inclusion of Children as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

AUTHORITY

42 U.S.C. 284a, sections 406 and [479] of the Public Health Service (PHS) Act, as amended, The National Diabetes and Digestive and Kidney Diseases Advisory Council (Council) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) and the Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, also referred to as Institute) on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

DESCRIPTION OF DUTIES

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for study, investigation, or research on basic and clinical diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country and, with the approval of the Director of NIDDK, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public.

The Council may prepare, for inclusion in the Biennial Report prepared by the Director, National Institutes of Health (NIH), under section 403 of the PHS Act, as amended (1) comments reflecting the activities of the Council in the fiscal years in which the report is prepared; (2) comments on the progress of the Institute in meeting its objectives; and (3) recommendations respecting the future directions and program and policy emphasis of the Institute.

AGENCY OR OFFICIAL TO WHOM TOHE COMMITTEE REPORTS

The Council will advise the Secretary; the Assistant Secretary for Health; the Director, NIH; and the Director, NIDDK.

SUPPORT

Management and support services will be provided by the Division of Extramural Activities,

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is $93,758. The estimated annual person-years of staff support required is 0.3, at an estimated annual cost of $49,807.

DESIGNATED FEDERAL OFFICER

The Director, NIDDK, will assign a full-time or permanent part-time NIDDK employee to serve as the Designated Federal Officer (DFO) of the Council. In the event that the DFO cannot fulfill the assigned duties of the Council, one or more full-time or permanent part-time NIDDK employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH, or Director, NIDDK.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Council will be held not less than three times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Council's functions, dates and places of meetings, and a summary of the Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing. This Council is mandated by statute with no specified end date.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the National Diabetes and Digestive and Kidney Diseases Advisory Council will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Council will consist of 18 members appointed by the Secretary and 6 nonvoting ex officio members: the Secretary; the Director, NIH; the Director, NIDDK; the Chief Medical Director of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs; and the Assistant Secretary for Science and Education, United States Department of Agriculture (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Of the 18 appointed members, 12 will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NIDDK, particularly representatives of the health and scientific disciplines in the areas of diabetes mellitus, endocrinology, metabolism, digestive diseases, nutrition, nephrology, urology, hematology and public health. Six of the members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. All non-Federal members will serve as Special Government Employees. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

Members will be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

The Chair of the Council will be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NIDDK, to be the Chair. The term of office of the Chair will be two years.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee /working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee will be three members. Ad hoc consultants do not count towards the quorum and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Department policies. Council and subcommittee records will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

October 31, 2012

APPROVED

9-15-12
Date

Director, NIH

NOTICE OF RECHARTER

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES
ADVISORY COUNCIL

The Council was established by statute and has functions which are of a continuing nature so that its duration is not governed by section 14(a) of the Federal Advisory Committee Act but is otherwise provided for by law. The Council is hereby rechartered in accordance with section 14(b)(2) of that Act.

5-15-98
Date

Director, NIH

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

> ***The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.***

How do I get started?
You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:**
https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement
4 Extension

5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution
8 Change of Institute or Division (noncompeting continuation)
9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR*, *NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available.

Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Teresa Lindquist, lindquit@niddk.nih.gov or 301-451-6418.

National Diabetes and Digestive and Kidney Diseases Advisory Council: Advisory Council Operating Procedures

(Pending Approval of NDDKAC)

September 2012
Expiration: February 2013

A. Purpose

This documents operating procedures established annually by the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) for use of council-delegated authorities. These authorities establish program management and council review procedures for the Institute's extramural programs and establish authorities for management actions undertaken by staff.

In general, the Council makes three types of recommendations relating to second level review of scientific review group (SRG) actions: (1) the Council can concur with the SRG critique; (2) it can suggest a different budget and/or a different length of the grant period; and (3) it can advise deferral of an application for re-review. Specific procedures are given below for each of these types of actions. These procedures are meant to ensure a level of uniformity and comparability across the Council's three subcommittees, which are aligned with the Institute's programmatic divisions. Those subcommittees of Council are free to develop and utilize their own procedures with the understanding that they be consistent with the operating procedures.

B. Background

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other National Institutes of Health (NIH) awarding Institutes are required by policy to establish procedures for interactions between Advisory Councils and the staff responsible for the day-to-day management of extramural portfolios. These procedures, referred to as Council-delegated authorities, govern staff and NDDKAC responsibilities with regard to grant portfolio management.

C. Definitions

1) ***Council Delegated Authorities***: Those actions negotiated between the NDDKAC and the Director, NIDDK that govern management of the Institute's extramural program portfolio.

2) ***En Bloc Action***: An action taken by Council on a group of applications under review rather than on specific individual applications being presented to NDDKAC for review.

3) ***Staff Actions*:** Actions that, based on policy and procedures, do not require a specific action on the part of the NDDKAC. These actions include, but may not necessarily be limited to: (a) change of grantee institution, (b) change of principal investigator, (c) administrative supplements, (d) no-cost extensions, and (e) phase-out or interim support.

4) ***Communication Letter:*** A communication between an applicant and Institute staff that is included for NDDKAC information purposes. Communication letters may or may not be acted upon by Council and need not be brought up for special discussion.

D. Policy and Implementation Procedures

The NDDKAC by approval has delegated authority to the NIDDK Director for staff to negotiate adjustments in dollars and/or the terms and conditions of grant and cooperative agreement awards recommended by the Council. In general, these operational guidelines for administrative actions are developed to provide a day-to-day framework for the smooth and effective operations necessary after review of grant applications by the Council. They are principally intended to enhance the administration of the federal assistance portfolio by the NIDDK.

NIDDK program and grants management staff analyze and review applications, i.e., noncompeting continuation applications and competing applications (new, resubmission (amended) renewal, or revision (supplemental) before issuing a grant award. NIDDK staff negotiates appropriate adjustments, when applicable, for such changes as the base used for recovery of facilities and administrative costs and/or legislatively imposed salary or other limits. Also, staff can make adjustments to reconcile inconsistencies between SRG recommended budgets and approved activities.

Administrative requests for increases in direct costs, which are the result of marked expansion or significant change in scientific content after formal peer review, will be referred to the Council for advice and recommendation. The NIDDK Director will determine whether the urgency is sufficient to warrant interim consultation with the Council by mail, e-mail, facsimile or telephone, instead of delaying action until the next Council meeting, or by mutual agreement, in rare instances the NIDDK Director may act on behalf of the Council as a whole.

Actions not requiring NDDKAC review or advice are: (1) change of grantee institution, (2) change of principal investigator, (3) administrative supplements to provide additional support either to meet the increased cost of maintaining the level of research previously recommended, or to accommodate activities or to meet needs judged by staff to be within the scope of the previously peer reviewed project, or (4) phase-out or interim support. The Council will be provided with notice of general solicitations for administrative supplements if they apply to an entire class of applications. In addition, NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided justification in a communication letter, and the restoration is in the best interest of the Institute and the project is of high programmatic relevance. Staff will record the action taken and its justification in a memo to the file. In addition, restorations will be summarized for Council information at the next regular scheduled meeting.

Each Council round Council will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under NIH policy. For each application on the list that may actually be funded, NIDDK staff will provide information about the other funding for the PI that brings his/her direct cost total to the $1 million threshold and a justification for considering funding. Council members will review these cases and indicate whether or not they have concerns.

NIH, in an effort to improve the efficiency of making awards, authorized the use of an expedited review process by initiating OER Policy Announcement 1999-01 entitled "Council Operating Procedure for Expedited En Bloc Concurrence." NIDDK makes use of an expedited concurrence of en bloc actions to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive and responsible manner.

All grant and cooperative agreement applications, excluding those from foreign organizations, which have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution) or need SCR, will follow a process of expedited concurrence whereby the review of applications is delegated by the

Chairman of the Advisory Council to designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee shall consist of the Council Executive Secretary (non-voting) and six members of the NDDK Advisory Council. Two members will be selected from each subcommittee of the NDDK Advisory Council.

The Executive Secretary will alert the concurrence committee members with responsibility for expedited concurrence when review outcomes for eligible applications are available in the Electronic Council Book. The Electronic Council Book enables members to access: Application Number, Principal Investigator, Project Title and Percentile/Priority Score. Typically this will occur once each Council round, several weeks before the scheduled NDDKAC meeting, however circumstances may arise that will require an additional, earlier expedited concurrence review to allow a set of applications to be funded in a timely manner to optimize the initiation or continuation of the proposed research. In the event of an earlier expedited concurrence review the same procedures described below will be followed including the involvement of the full NDDKAC.

Electronic or written concurrence by a minimum of two members with no votes for non-concurrence within seven days of notification of posting is required for expedited concurrence approval. Any member may bring an application to full NDDKAC consideration without the need for justification. Any single vote for non-concurrence within the allotted time period will result in that application going for regular consideration to the NDDKAC under its normal procedures for concurrence. Members not acting upon an application within the allotted time period after posting will be considered to have abstained from a vote on that application. Expedited listings lacking enough votes for final action will be presented to the regular NDDKAC meeting for review.

The full NDDKAC will be provided with a list of all applications eligible for expedited concurrence, as well as the outcome of the vote by the concurrence committee members on those applications. The Executive Secretary will report the expedited concurrence recommendations during the closed session of the full Advisory Council meeting when reviewed applications are discussed.

The NDDKAC also advises the Institute on: The adequacy of the initial review process, including appeals to grant application review; nominations for and extensions of, Method to Extend Research in Time (MERIT) awards; and, funding of applications with Special Emphasis dollars. Finally, the NDDKAC will receive a report annually on the activities of the NIDDK Board of Scientific Counselors.

E. Exceptional Situations

As circumstances require, based on programmatic considerations, the Director, NIDDK after consultation with Council, may make exceptions to these guidelines.

Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures across extramural divisions. Nonetheless, circumstances may require the deviation from the prescribed procedure in order to achieve the mission of the NIDDK. By NDDKAC delegated procedures, the Director, NIDDK has authority to act upon unusual or extenuating circumstances. These actions are usually discussed by a subset of Council members selected by the Director and Executive Secretary of NDDKAC. Any actions of this exceptional nature must be appropriately documented as necessary for the official record, and should be reported to Council at its next scheduled meeting.

F. References

1) Public Health Service Act as amended, 42 USC 52h, 42 USC 241, 42 USC 284a

2) NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management (http://www1.od.nih.gov/oma/manualchapters/management/1805/)
3) NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for NIH Special Government Employee SGE Advisory Committee Members (http://www1.od.nih.gov/oma/manualchapters/management/1810-1/)
4) NIH Manual Chapter 3005, Review and Evaluation of Intramural Programs (http://www1.od.nih.gov/oma/manualchapters/intramural/3005/)
5) NIH Manual Chapter 4204-204B, Peer Review Process (http://oma.od.nih.gov/manualchapters/grants/4204-204B/)
6) NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organizations (http://oma.od.nih.gov/manualchapters/grants/54104/)
7) NIH Manual Chapter 54206, Responsibility for Care and Use of Animals (http://oma.od.nih.gov/manualchapters/contracts/6380-2/)
8) NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities (http://oma.od.nih.gov/manualchapters/grants/54513/)
9) NIH Manual Chapter 7410, Review and Documentation of Protections for Human Subjects in Grant Applications and Contract Proposals (http://oma.od.nih.gov/manualchapters/comgc/7410/)
10) OER Policy & Guidance: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page (http://grants.nih.gov/grants/funding/women_min/women_min.htm)
11) OER Policy & Guidance: Inclusion of Children Policy Implementation (http://grants.nih.gov/grants/funding/children/children.htm)
12) NOT-OD-12-140: Notice of Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html)

National Diabetes and Digestive and Kidney Diseases Advisory Council Membership

(All terms end October 31 of year in parentheses)
(Subcommittee membership also shown in parentheses after name)

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Advisory Council Meetings Dates: 2013 - 2014

2013
February 13-14 (Wednesday and Thursday)
May 15-16 (Wednesday and Thursday)
September 26-27 (Thursday and Friday)*
Building 31, Conference Rooms 10, 6, and 7

*Note divergence from familiar Wednesday/Thursday schedule

2014
February 5-6 (Wednesday and Thursday)
May 14-15 (Wednesday and Thursday)
September 3-4 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6, and 7

Sample NDDKAC Agenda

191st Meeting of the
NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

Building 31, C Wing, 6th Floor, Conference Room 10

February 13th 2013

OPEN SESSION 8:30 a.m. to 12:00 noon

I. CALL TO ORDER — **Dr. Rodgers**

II. CONSIDERATION OF SUMMARY MINUTES OF THE 190th COUNCIL MEETING — **Dr. Rodgers**

III. FUTURE COUNCIL DATES — **Dr. Rodgers**

2013
May 15-16 (Wednesday and Thursday)
September 26-27 (Thursday and Friday)*
**Note divergence from familiar Wednesday/Thursday schedule*

2014
February 5-6 (Wednesday and Thursday)
May 14-15 (Wednesday and Thursday)
September 3-4 (Wednesday and Thursday)

Building 31, Conference Rooms 10, 6 and 7

IV. ANNOUNCEMENTS
Confidentiality/Conflict of Interest — **Dr. Stanfield**

V. REPORT FROM THE NIDDK DIRECTOR — **Dr. Rodgers**

VI. UPDATE FROM THE DIRECTOR, NCATS — **Dr. Austin**
Vision for NCATS and Possible Interactions with NIDDK

VII. COFFEE BREAK 10:00 a.m.

VIII. UPDATE FROM THE DIRECTOR, NHLBI — **Dr. Gibbons**
Vision for NHLBI and Possible Interactions with NIDDK

IX. SCIENTIFIC PRESENTATION
The LIN28b-Let-7 Axis in Intestinal Epithelial Biology **Dr. Rustgi**

X. SUBCOMMITTEE MEETINGS

1:00 to 4:00 p.m.

Diabetes, Endocrinology, and Metabolic Diseases
Building 31, C Wing, 6th Floor Conference Center, Room 10

Closed Session: 1:00 p.m. – 2:30 p.m.
Open Session: 2:30 p.m. – 4:00 p.m.

Digestive Diseases and Nutrition
Building 31, C Wing, 6th Floor Conference Center, Room 6

Open Session: 1:00 p.m. – 2:30 p.m.
Closed Session: 2:30 p.m. – 4:00 p.m.

Kidney, Urologic, and Hematologic Diseases
Building 31, C Wing, 6th Floor Conference Center, Room 7

Open Session: 1:00 p.m. – 3:00 p.m.
Closed Session: 3:00 p.m. – 4:00 p.m.

CLOSED SESSION 4:15 p.m. to 4:30 p.m.

XIII. REPORTS OF SUBCOMMITTEES: CONSIDERATION OF APPLICATIONS **Dr. Stanfield**

Diabetes, Endocrinology, and Metabolic Diseases
Digestive Diseases and Nutrition
Kidney, Urologic, and Hematologic Diseases

XIV. ADJOURNMENT **Dr. Rodgers**

Sample of NDDKAC Meeting Minutes

Meeting Minutes
Department of Health and Human Services
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
September 12, 2012

I. CALL TO ORDER

Dr. Griffin Rodgers, Director, NIDDK, called to order the 190th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m., Wednesday, September 12,2012, in the Natcher Conference Center (Building 45), Conference Rooms E1/E2, on the NIH campus in Bethesda, Maryland.

A. ATTENDANCE - COUNCIL MEMBERS PRESENT

Dr. Domenico Accili
Ms. LaVarne Burton
Dr. Judy H. Cho
Dr. Robert C. Flanigan
Dr. Christopher K. Glass
Dr. Gregory J. Gores
Ms. Jane Holt
Ms. Judy M. Hunt
Dr. Francine R. Kaufman
Dr. Kenneth Kaushansky
Dr. David M. Klurfeld
Ms. Robin Nwankwo
Dr. Jerry P. Palmer
Dr. Thomas N. Robinson
Dr. Anil K. Rustgi
Dr. John R. Sedor
Dr. Alan R. Shuldiner
Dr. William D Steers
Mr. John W. Walsh
Dr. Mark L. Zeidel

Also Present:
Dr. Griffin Rodgers, Director, NIDDK, and Chairperson, NIDDK Advisory Council
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

B. NIDDK STAFF AND GUESTS

Abankwah, Dora – NIDDK
Abraham, Kristin – NIDDK
Agodoa, Lawrence – NIDDK
Appel, Michael – NIDDK
Arreaza, Guillerno – NIDDK
Appel, Michael – NIDDK
Arreaza, Guillerno – NIDDK
Barnard, Michele – NIDDK.
Begum, Najma – NIDDK
Bishop, Terry – NIDDK
Bleasdale, John – CSR
Blondel, Olivier – NIDDK
Brown, Sheny – NIDDK
Buchanan, Sarah – Nephrology Care FDN
Burnett, Arthur – NIDDK
Calvo, Francisco – NIDDK
Camp, Dianne – CSR
Carrera, Krysten – NIDDK
Carrington, Jill – NIDDK
Castle, Arthur – NIDDK
Cleffi, Katie – Resch. Triangle Inst.
Connaughton, John – NIDDK
Copeland, Randy – NIDDK
Cowie, Catherine – NIDDK
Davila-Bloom, Maria – NIDDK
Dayal, Sandeep – NIDDK
Densmore, Christine – NIDDK
Doherty, Dee – NIDDK

Donohue, Patrick - NIDDK
Doo, Edward – NIDDK
Eggerrnan, Thomas – NIDDK
Eggers, Paul – NIDDK
Erhardt, Britt – NIDDK
Evans, Mary – NIDDK
Everhart, James – NIDDK
Farishian, Richard – NIDDK
Fonville, Olaf – NIDDK
Fradkin, Judith – NIDDK
Gansheroff, Lisa –NIDDK
Garte, Seymour – CSR
Gill Christine – NIDDK
Giambarresi, Leo – Am Urol Assn
Goter-Robinson, Carol – NIDDK
Grraves, Reed – CSR
Grey, Michael – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hamilton, Frank – NIDDK
Hanlon, Mary – NIDDK
Hardy, Dianne – CSR
Hoff, Eleanor – NIDDK
Hoofnagle, Jay – NIDDK
Horlick, Mary – NIDDK
Hoshizaki, Deborah – NIDDK
Howards, Stuart – NIDDK
Hubbard, Van –NIDDK
Hunter, Christine – NIDDK
Hunter, Helen — NIDDK
Hyde, James – NIDDK
Hypes, Brinkley – OHR, OD
James, Stephen – NIDDK
Jenkins, Connien – NIDDK
Jerkins, Ann – NIDDK
Jones, Teresa – NIDDK
Karp, Robert – NIDDK
Karimbakas, Joanne – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul. – NIDDK
Kirkali, Ziya – NIDDK
Kranzfelder, Kathy – NIDDK
Krause, Michael – NIDDK
Krishman, Krish – CSR
Kuczmarski, Robert – NIDDK
Kusek, John – NIDDK
Laughlin, Maren – NIDDK
Lescheck, Ellen – NIDDK
Malik, Karl – NIDDK
Malozowski, Saul – NIDDK
Margolis, Ron – NIDDK
Maruvada, Padma – NIDDK
Martey, Louis – NIDDK
McKeon, Catherine – NIDDK
McKeython, Miya — OD
Miller, David – NIDDK
Miller, Megan – NIDDK
McNally, James – NCI
Miller, Megan – NIDDK
Moxey–Mims, Marva – NIDDK
Mowery, Penny — NIDDK
Mullins, Christopher – NIDDK
Murphy, Shawn – RPDR Partners Healthcare
Narva, Andrew – NIDDK
Newman, Eileen – NIDDK
Olan, Grant– Am Soc Nephrology
Patel, D. G. – NIDDK
Pawlyk, Aaron – NIDDK
Peters, Craig – Children's Natl Hosp
Polglase, William – NIDDK
Rankin, Tracy – NIDDK
Rodrigues, Michele – SRI Internatl.
Rosendorf, Marilyn – NIDDK
Rushing, Paul – NIDDK
Salaita, Christine – NIDDK
Salomon, Karen – NIDDK
Sankaran, Lakshmanan – NIDDK
Sanovich, Elena – NIDDK
Sato, Sheryl – NIDDK
Savage, Peter – NIDDK
Scanlon, Elizabeth – NIDDK
Schmitt, Jill – NIDDK
Sechi, Salvatore — NIDDK
Serrano, Jose – NIDDK
Sherker, Averell – NIDDK
Shepherd, Aliecia – NIDDK
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Star, Robert – NIDDK
Staten, Myrlene – NIDDK
Tatham, Thomas – NIDDK
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Van Raaphorst, Rebekah – NIDDK
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Watson, Joanna – NCI
Wellner, Robert – NIDDK
Williams, Shimere Lewis Burke Assoc
Wright, Daniel – NIDDK
Wright, Elizabeth - NIDDK

C. ANNOUNCEMENTS

Dr. Rodgers made the following announcements:

Retiring Council Members

Dr. Rodgers recognized four Council members who were completing their terms and rotating off the Council with the September 2012 meeting. He thanked them for their service to the NIDDK and the NIH.

Ms. LaVarne Burton is President and Chief Executive Officer of the American Kidney Fund (AKF). Ms. Burton provided the Council with expertise in community outreach and education, and shared the perspectives of patients. She promoted collaboration between the NIDDK and the AKF including involvement in the roll-out of a "Pair Up" initiative designed to empower women to protect themselves, family, and friends from kidney disease. She helped to focus research efforts addressing health disparities.

Dr. Robert Flanigan serves as the Department Chairperson and a Professor of Urology at Loyola University. He is also a practicing physician and is active in multiple community health education and outreach activities. He provided the Council with a broad range of expertise in clinical urology and urology research. Dr. Flanigan helped the NIDDK develop initiatives and solutions to address concerns about pipeline and training issues.

Dr. Christopher Glass is Professor, Department of Cellular and Molecular Medicine, Department of Medicine, University of California, San Diego. He brought to the Council expertise in basic research, including gene expression. His scientific acumen and sound judgment contributed to the discussion of issues of importance to the NIDDK. Dr. Glass provided wise counsel to the Institute as it is striving to maintain quality and cutting-edge science in the face of resource constraints.

Dr. John Sedor is Associate Chair for Research, Department of Medicine, MetroHealth Medical Center Campus, Case Western Reserve University. Dr. Sedor provided the Council with expert advice in both basic and clinical nephrology, especially the pathophysiology and genetics of chronic kidney disease. He has been a tireless advocate for the training of junior investigators. Dr. Sedor also serves as an advisor to a number of large NIDDK studies, and he played a key role in supporting the NIDDK's on-line strategic planning effort, the Kidney Research National Dialogue.

Awards

Ms. Robin Nwankwo, an NIDDK Council member, has received the America Diabetes Association's (ADA) Outstanding Educator in Diabetes Award in recognition of her educational efforts in the field of diabetes and significant contributions to the understanding of diabetes education. As a diabetes educator and researcher at the University of Michigan Medical School, Ann Arbor, Ms. Nwanko has been a contributor to the development and implementation of empowerment-based educational research studies among urban African Americans. Her current work is a randomized, controlled feasibility trial of church-based diabetes education and peer support.

"In Memoriam"

Dr. John Stokes, who contributed to several NIH clinical research activities, has passed away. His roles at the University of Iowa included Professor, Executive-Vice-Chair for the Department of Internal Medicine, and Director of the Division of Nephrology. He coordinated the University of Iowa site of an NIH clinical trial on nocturnal dialysis. He also led in the planning and execution of many other seminal, multicenter NIH-sponsored clinical trials in nephrology. Dr. Stokes provided *ad-hoc* advice to the NIDDK on numerous occasions, and his expertise will be missed by the research community.

NIDDK Staff Members

Dr. Paul Eggers, Senior Scientific Officer for Kidney and Urology Epidemiology Programs, will be retiring from the NIDDK's Division of Kidney, Urologic and Hematologic Diseases. During his 12 years with the NIDDK, Dr. Eggers contributed to the United States Renal Data System (USRDS), the Urologic Diseases in America (UDA) project, the Boston Area Community Health Study (BACH), the Data Center for the NIDDK Repository, and other efforts.

Dr. Jill Smith is joining the Division of Digestive Diseases and Nutrition as Program Director for Clinical and Translational Research in Digestive Diseases. Following her graduation from the University of Florida School of Medicine, Dr. Smith completed training in Internal Medicine and a Fellowship in Gastroenterology at the University of Missouri.

I. CONSIDERATION OF SUMMARY MINUTES OF THE 189th COUNCIL MEETING

Dr. Rodgers

Following a motion that was made and seconded, the Council approved, by voice vote, the Summary Minutes of the 189th Council meeting, which had been sent to them earlier for review.

II. FUTURE COUNCIL DATES

Dr. Rodgers

Dr. Rodgers reminded the Council of future meeting dates.

2013
February 13-14 (Wednesday and Thursday)
May 15-16 (Wednesday and Thursday)
September 26-27 (Thursday and Friday)*****
Building 31, Conference Rooms 10, 6 and 7
*** The divergence from the familiar Wednesday and Thursday schedule was noted.**

2014
February 5-6 (Wednesday and Thursday)
May 14-15 (Wednesday and Thursday)
September 3-4 (Wednesday and Thursday)

Building 31, Conference Rooms 10, 6 and 7

The NIDDK expects that most meetings will be a single day. However, Council members were asked to hold two days for each meeting to ensure flexibility should a situation arise where a longer meeting is required.

IV. ANNOUNCEMENTS
Dr. Stanfield

Confidentiality

Dr. Stanfield reminded Council members that material furnished for review purposes and discussion during the closed portion of the meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict of Interest

Dr. Stanfield reminded the Council that advisors and consultants serving as members of public advisory committees, such as the Council, may not participate in situations in which any violation of conflict of interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that a member does not participate in, and is not present during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected.

To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Dr. Stanfield noted that each Council member's folder contains a statement regarding the conflict of interest in his or her review of applications. He asked each Council member to read it carefully, sign it and return it to the NIDDK before leaving. Council members were reminded that, at Council meetings when applications are reviewed in groups without discussion, that is, "*en bloc*" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict. With regard to multi-campus institutions of higher education, Council members were reminded that an employee may participate in any particular matter affecting one campus of a multi-campus institution of higher education, if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

Special Council Review

Dr. Stanfield said that the NIH has established a new policy for Special Council Review, which requires the Council to give additional consideration to applications from Principal

Investigators who have more than $1 million in direct costs annually from active NIH Research Project Grants (RPGs). Prior to each Council meeting, the Electronic Council Book will provide members with a list of competing applications that meet the criteria for this Special Council Review. For each application on the list that may actually be funded, NIDDK staff will provide information about the other funding for the Principal Investigator that brings his/her direct cost total to the $1 million threshold, and a justification for considering funding. Council members will review these cases and indicate whether or not they have concerns.

Approval of Revised Council Operating Procedures

Dr. Stanfield said that, from time to time, a need arises for the NIDDK to revise the Council Operating Procedures prior to their annual update at the winter Council meeting. He stated that these circumstances have occurred and that revised Council Operating Procedures were therefore included for the Council's review in the pre-meeting materials in the Electronic Council Book, and they were also included in the members' meeting folders at the conference table. The NIDDK needs to modify the Procedures with respect to the following:

- To add procedures for the Special Council Review;
- To accommodate special circumstances for an "earlier" early concurrence of applications on time-sensitive announcements such as the recently published 'Time-Sensitive Obesity Policy and Program Evaluation" Program Announcement;
- To remove the section on the NIDDK's review of applications for the National Center for Advancing Translational Science (NCATS), which now has its own Council;
- To update references to NIH Manual Chapters.

In the absence of any questions or comments, and pursuant to a motion that was made and seconded, the Council approved the revised Operating Procedures by voice vote.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Rodgers

Update on Fiscal Year 2013 Appropriations Bills

Dr. Rodgers reported that, at the time of the September 2012 Council meeting, the Congress had not cleared any of the Fiscal Year 2013 appropriations bills, including the Labor-Health and Human Services bill that funds the NIH and several other agencies. Dr. Rodgers reported on congressional action with respect to that bill.

On the Senate side, the full appropriations committee passed a bill in June that would fund the NIH at the level of $30.723 billion, an increase of about $100 million over the previous fiscal year. The funding level for the NIDDK would be about $2 million above its previous year's budget of $1.797 billion.

On the House side, a spending bill has passed the relevant appropriations subcommittee, but has not yet been acted upon by the full committee. It would provide $30.6 billion for the NIH, which is essentially equivalent to both the Fiscal Year 2012 appropriation and the President's request for Fiscal Year 2013. Funding for most Institutes would be reduced by about 0.02 percent from the previous year's levels. Dr. Rodgers noted that the House

appropriations subcommittee's bill contains quite of bit of prescriptive language regarding the allocation of resources, as well as a system for assuring that research activities are of significantly high scientific value and would have a measurable impact on public health.

With the end of the fiscal year fast approaching, it is unlikely that the NIH will receive funding through a regular appropriations bill. Rather, one or more temporary spending measures, so-called Continuing Resolutions, are likely to provide initial Fiscal Year 2013 funds for agencies whose regular appropriations bills have not been enacted. A six-month Continuing Resolution has been introduced in the House, but it awaits Senate action. Such a short-term funding measure would remove some spending issues from the pre-election debate. It may also help to avoid the threat of a government shutdown during the lame duck session of the Congress that occurs between the national election and the Presidential Inauguration.

Update on Possible Sequestration

Dr. Rodgers updated the Council on the implications of possible across-the-board reductions in federal spending. As mandated by law, these reductions, which are referred to as a sequestration of funds, would commence in January 2013 unless legislation is enacted to reduce the national deficit by specified amounts. If sequestration occurs, Federal agencies are expected to lose about 7.8 percent from their Fiscal Year 2013 budgets. The NIH would lose an estimated $2.39 billion, which would bring success rates for grant applications to historically low levels. The Sequestration Transparency Act requires the President to provide the Congress with a report on the percentages and dollar amounts that would be cut from discretionary and mandatory spending accounts at the program, project and activity levels, as well as a list of accounts that are exempt from cuts. The report has not yet been submitted.

VI. "Outstanding Productive Investigator Umbrella Award"

Dr. Robert Star, Director, Division of Kidney, Urologic and Hematologic Diseases, NIDDK

Dr. Star requested the Council's input regarding a very preliminary idea that the NIDDK has been exploring with other Institutes. He presented the conceptual framework for a possible new program of "Outstanding Productive Investigator Umbrella Awards." Such a program is currently under discussion as a potential collaborative effort with the National Cancer Institute (NCI). The concept is based in principle on the NCI's Outstanding Investigator Program, which was created in 1985 after the President's Cancer Panel recommended that a way be found to provide more secure funding for established investigators. The NCI's Program was terminated in 1995, and it was never evaluated. The new umbrella award concept has engendered considerable debate--both pro and con--and the NIDDK is eager to have the Council's views.

The intent of the umbrella award concept is to provide stable, long-term funding to an entire laboratory, thereby permitting investigators to bundle their current awards into a single, renewable grant. The umbrella awards would enable a laboratory's investigators to coalesce in the pursuit of innovative, creative, and high-risk/high-impact research. That type of research tends to require stable, long-term funding that is not usually available in the current fiscal environment. As a result, investigators now devote substantial amounts of time to the

continuous process of writing multiple grant applications--a process that can diminish productivity and creativity and lead to negative attitudes toward research.

Dr. Star described some of the key features of the umbrella award concept. Awards are envisioned as being eight-to-ten year R35 grants, with a midpoint retrospective review. They could be renewed as long as the program existed. To be eligible to apply, investigators would need to be continuously funded, highly productive, substantial contributors to science. Importantly, they would need to agree to devote perhaps as much as 75 percent of their time to the effort, and their institutions would also need to make a major commitment--perhaps at least 25 percent of a Principal Investigator's salary. In a Letter of Intent, applicants would document that they meet the eligibility requirements; indicate how research would be bundled within their laboratory; and demonstrate that the work is within the NIDDK mission.

The peer review process for umbrella awards would be similar to that for the NIH Intramural Research Program and the Howard Hughes Medical Institute. The review would be conducted by a Special Study Section, with approximately eighty percent of the review focused on the assessment of research already conducted, including its importance, progress, and impact. About twenty percent of the review would center on the applicant's proposed general framework for planned research. The review for umbrella awards would therefore be quite different from the current NIH review system for extramural grants, which primarily focuses on a prospective review of detailed research ideas proposed in individual applications. If selected for an umbrella award, an investigator would relinquish all current individual investigator-initiated projects and accept a small reduction in overall funding--on the order of perhaps 10 percent. This reduction would be a tradeoff for the long-term funding stability provided by an umbrella award.

Dr. Star pointed out some of the potential benefits of umbrella awards. Investigators could spend more time conducting science and less on writing grants. Their research could therefore be more focused and creative. As a result, they would have more positive attitudes about their research careers to convey to trainees. Institutions would benefit from receiving these prestigious awards, and the NIH would have fewer grants to review.

In closing, Dr. Star put forth some of the questions on which the NIDDK is seeking the Council's views:

- What would be the overall impact of establishing an umbrella award program?
- What should be included in the program's design elements, including eligibility criteria (e.g., career stage, funding level, and laboratory size); what kinds of grants would be bundled; would investigators be precluded from submitting additional bundled grants?
- Would Principal Investigators and institutions want this award?
- What would investigators be willing to relinquish for more stable, long-term funding?
- What review issues would exist or might arise?
- What should be the degree of required institutional commitment?
- Should an umbrella award program replace the MERIT award program?
- What percent of the budget for research project grants should be allocated to an umbrella award program?
- Should grants be bundled across participating Institutes and Centers and/or the Intramural Research Program?
- What would be overall perceptions regarding the fairness of an umbrella award program? Is it the wrong time to start such a program?

Dr. Star noted that the issues of perceived fairness and the appropriate timing of an umbrella award program are particularly important because the new program would make larger grants than those possible through the R01 grant mechanism. If a decision is made to move forward with an umbrella award program, the next steps would be to issue a Request for Information to gauge interest in the research community, and to work with the NCI and other Institutes and Centers to refine the concept further.

Council Questions and Discussion

Program Goals and Potential Benefits: *The nurturing of better science should be the primary goal. It is hoped that goal will be furthered by freeing highly creative scientists from the continuous burden of collecting perfunctory preliminary data needed for writing frequent grant applications. Another benefit may be the removal of established investigators from the R01 pool so that younger investigators can have greater opportunities to compete successfully in that pool.*

Possible Limitations on Award and Program Size: *How many NIDDK grantees would be eligible for an umbrella award? Would there be a limit on the total number of awards the program would make? Should there be a few large awards, such as four to six, or a larger number of small awards? Should there be a cap on program growth?* Dr. Star said that decisions would need to be made about the funding threshold for investigators, and about the overall size and growth of the program. Regarding possible funding thresholds, he presented a graph showing examples of thresholds reached by NIDDK investigators at points in time from 2007-2011. For example, for two years during that time period, 46 investigators reached a threshold of $1 million in funding; 22 reached a threshold of $1.2 million; and ten reached a threshold of $1.5 million.

Possible Limitation on Duration of Awards: *Because science changes rapidly, it may be inadvisable to commit funds for long periods of time. There is a danger that long-term funding programs for senior scientists can perpetuate fading ideas and cause a generation of younger scientists to forsake a research career. The data show that many NIDDK investigators who reach the $1 million funding threshold do not sustain that level of funding over the long term; yet, the umbrella award would lock in "gold-star" funding status for up to ten years. In times of fiscal constraints, the NIH needs the greatest possible flexibility to pursue emerging opportunities, not long-term fiscal commitments. If the umbrella program is initiated, consideration should be given to shorter award periods.* The NIDDK staff said that, according to the NCI's experience, investigators will not apply if the award period is too short. Moreover, the NIH staff who developed the idea for the umbrella awards would like to find ways to focus on younger investigators.

Practical Issues for Investigators with Multiple R01s Who Are Likely to Meet a High Funding Threshold: *It would be difficult for investigators who hold multiple R01 awards to sustain creativity with funding levels less than they currently receive, especially if there are no inflationary increases. They would therefore be likely to seek other sources of support. Moreover, investigators with multiple R01s probably received them from several Institutes, and that complexity would raise funding and management issues in an umbrella award program.*

Review of Umbrella Awards: *How will reviewers assess productivity and innovation? Currently, the most favorable peer review scores don't necessarily correlate with the most innovative science. Could a retrospective assessment of publications be performed? Would it be necessary to have totally different review criteria for this award, and if so, would it be possible to change the culture and behavior of peer reviewers so that they will apply the new criteria?*

NCI Outstanding Investigator Award Program: *What are the views of this terminated program?* Dr. Star replied that, although the NCI program was never evaluated, it was very popular among investigators and institutions. There were also administrative efficiencies and cost savings. However, the program experienced some problems that the NIDDK would take steps to prevent. For example, the program had a large, non-competing base of funding that grew to be a substantial percentage of the NCI's research project grant budget at the expense of other programs. The NIDDK would address this issue by funding only 85-90 percent of the R01 budgets that are bundled under the umbrella award program. The NCI program also included non-NCI R01 awards; however, the NIDDK would place a limit of one umbrella award on any participating Institute or Center, or have that entity pay its proportional share of costs. Because the NCI program found that investigators had difficulty re-entering the R01 pool when their R35 grants ended, the NIDDK would plan to offer a bridge award. While the NCI program lacked evaluation, the NIDDK's umbrella award program would definitely include an evaluation component.

Re-entry to R01 Investigative Pool: *Given that the NCI Outstanding Investigators had difficulty re-entering the competition for R01 awards, it may be advisable to heavily emphasize the mid-point review planned for the umbrella award. Also, if investigators do not receive a favorable review at the midpoint of the award, would resources be provided at that point to help them prepare for R01 competition?* NIDDK staff said that there would be some type of bridge support for investigators who did not have favorable reviews at the five-year mark.

Institutional Response: *It would be difficult for institutions to commit 25 percent of the salaries of investigators who receive umbrella awards. It remains to be seen whether institutions could preclude their investigators from applying for such prestigious awards.*

Perceptions: *Perceptions are important, especially among young investigators who are already struggling for NIH funding. Would this award be perceived as a mechanism for favoring well-funded, established investigators, while shutting out newer, younger researchers? Would investigators funded through umbrella awards also be eligible for similar long-term funding through the Howard Hughes Medical Institute, thus adding to perceptions that they are monopolizing funds? Would the umbrella award be targeted to investigators at certain stages of their careers so that it does not turn out to be a terminal award prior to retirement? Assuming that the NIDDK continues to have fairly flat budgets, wouldn't the creation of an R-35 funding pool for umbrella awards reduce the percentage of Institute funds used to support R01 grants? Investigators look at the way Institutes allocate their budgets among research mechanisms and they may make career choices accordingly. To reduce misunderstandings about the program, it would be important to underscore that the umbrella award program would not require new funds, but rather, the repositioning of funds currently committed to R01 grants.*

Timing: *Given current fiscal constraints and uncertainties, it may not be the most propitious time to undertake a new umbrella award program.*

VII. "NIDDK Centers Program Review: Final Report"
Dr. Gregory Germino, Deputy Director, NIDDK

Dr. Germino's presentation highlighted the multi-stage, broadly consultative Program Review of NIDDK's Research Centers Program, about which the Council had received previous updates. Dr. Rodgers announced the availability of a final report—emphasizing that it is not a stopping point, but rather, a transition to a next phase of activity.

Dr. Germino provided a summary of the recently completed NIDDK review its Research Centers Program, which currently funds 87 Centers for a total of about $100 million annually. He highlighted the process of the Program Review, its findings, and some of the actions the NIDDK is currently considering or has already taken in response to the findings, and the input and recommendations received. A final report has been provided to the Council and is available on the NIDDK web site. (http://www2.niddk.nih.gov/Research/Centers/NiddkCtrsPrgReview.html)

The purposes of the Program Review included: to strengthen a major NIDDK program; to ensure that resources are being used effectively and efficiently; to examine outcomes of a 2003 evaluation; and to address Council's February 2010 suggestions to enhance the program. These suggestions included taking steps to promote synergies and interactions; broaden access to research cores; and examine the value of pilot and feasibility studies.

As a backdrop, Dr. Germino pointed out several characteristics of the NIDDK's Centers Program. The Centers are typically based at institutions where clusters of investigators have related research interests that address a specific theme or scientific discipline of importance to the NIDDK. The broad goals of Centers include: to further collaborative, focused, multi-disciplinary research programs; to promote research training and the development of junior investigators; to leverage and maximize NIDDK resources; to provide flexible, dynamic support for high-risk/high-reward science; and to create synergies that accomplish more through centralized funding than would be achieved if the same funds were awarded to individual investigators. Components of Centers include administrative and scientific "cores," which provide centralized resources; pilot and feasibility (P&F) programs; and enrichment activities--all of which are used by dozens of participating researchers with related scientific interests at a given Center.

Program Review Process

Dr. Germino described the following major points in the Program Review process:

Internal Portfolio Review and Identification of Site-Visit Locations: As a first step, the NIDDK conducted a portfolio review of the Centers with respect to components of the Program, activities being funded, and geographic distribution of the Centers nationally. Based on this review, the NIDDK decided to conduct site visits at 25 Research Centers that were representative of the types of Centers in the Program. These Centers are located at five universities at which NIDDK resources are concentrated; opportunities for synergy are great; and site visits could be conducted efficiently. The identified institutions were: the University

of Pennsylvania/Children's Hospital of Philadelphia; Yale University; Washington University, St. Louis; the University of Washington/Fred Hutchinson Cancer Research Center/Seattle Children's Hospital; and Vanderbilt University.

Site Visits: From December 2010 through March 2011, the NIDDK conducted site visits at the Centers. To facilitate the site visits, the Institute provided a list of questions and discussion topics in advance. The visits included a detailed review of the research cores, meetings with Center Directors and institutional leaders, and information-gathering about pilot and feasibility activities. The NIDDK did not request that information be provided in a standardized format because the Program Review process was not an audit. Rather, the Institute wanted to see how the Centers were interpreting their mission. The semi-quantitative and qualitative information obtained was later aggregated without attribution to any individuals or specific Centers or institutions.

Interim Report and Comment Periods: In May 2011, the NIDDK presented to the Council an interim status report. During November and December 2011, the NIDDK solicited and integrated comments on an interim draft report from all the Centers in the Program, not just those that were site-visited. During May and June 2012, the NIDDK solicited and integrated public comments on the draft report using the Institute's web site. Both comment periods focused on discussion topics under consideration.

Final Report: Based on the input and comments received, the NIDDK prepared a final report to present to the Council in September 2012, and to make publicly available on the Institute's web site. The report contains information from three main sources: the NIDDK portfolio review; the site visits; and input received during the two comment periods.

Highlights of Final Report

The Program Review identified many strong elements of the NIDDK Centers Program and showcased how the Centers are advancing research progress on diseases within the NIDDK mission. The Program Review also identified areas that could be strengthened.

Dr. Germino summarized key points from the final report, which is organized by discussion topics. He highlighted the NIDDK's consideration of and responses to the findings, input and recommendations. He emphasized that the NIDDK wants to enhance the Centers Program in ways that will avoid introducing program changes that would place undue administrative burdens on the Centers or unnecessarily limit their flexibility.

Discussion Topic 1: Enhancing Synergy and Center Value:
Findings: Both the site visits and the two comment periods provided many tangible examples of synergy among the Centers, such as co-sponsorship of retreats and courses, co-support of research cores, and the participation of Center Directors in activities with other Centers and institutions. The NIDDK recognized that there are opportunities for synergism that have not yet been fully explored because the site visits themselves were the first interaction among all NIDDK-funded Centers at the participating institutions, as well as a means through which NIDDK staff members shared important experiences and knowledge. There was general support for enhancing coordination and promoting synergy to reduce costs and leverage resources in the pursuit of better science, especially in times of limited budgets.

Recommendations: The NIDDK is considering several steps, including the following: (1) enhancing synergy and Center value through the use of web-based tools, such as using the NIDDK web site as a source of information about Centers and their available resources; (2) having trans-NIDDK meetings of Center Directors and larger groups of investigators if a specific topic/need is identified; (3) identifying shared areas of research activity and opportunities for synergy with other programs, such as Clinical and Translational Science Award programs and research training programs; and (4) incentivizing Centers to build networks and share resources, possibly by including the consideration of such activity in NIDDK funding decisions.

Discussion Topic 2: Strengthening the Pilot and Feasibility Programs:

Findings: The NIDDK found that Research Centers are strongly committed to Pilot and Feasibility (P&F) components, which they consider very valuable and successful. Most P&F funds are distributed internally within each Center; however, some Centers have found ways to involve a broader base of investigators. According to the Centers, a major barrier to making external P&F awards is transferring indirect costs to another institution. The Centers reported important advantages and strengths resulting from their flexibility to administer aspects of their P&F programs, such as the application criteria, funding amounts, and numbers and durations of awards. Regarding eligibility for P&F awards, there was general support for the current approach, which primarily supports either established investigators who are changing research directions, or early-stage investigators who are entering a scientific discipline. There were some suggestions for broadening eligibility to other groups such as investigators who just missed the payline and need data to resubmit applications, or groups doing larger collaborative projects.

Recommendations: The NIDDK has concluded that the current definition of investigators eligible for P&F funding is appropriate and should be maintained. There are other mechanisms available to investigators with special needs. Rather than mandate administrative changes in response to suggestions, the NIDDK is planning to develop a "best practices" document that would address several issues such as the attention given to mentoring and to monitoring the progress of awardees. This document would also provide some guidance with respect to balancing types of P&F awards, such as awards for high-risk/high-reward science relative to awards for the career development of young investigators. The Institute generally agrees with comments that it is worthwhile, when possible, to open up the P&F component to investigators external to the Centers' home institutions in order to increase the competitive pool and share resources with the broader investigative community. The NIDDK will include in the "best practices" document examples of the approaches that some Centers have taken to make external P&F awards.

Discussion Topic 3: Core Support and Access:

Findings: The NIDDK found many examples of the value provided by research cores, such as furthering the access of many investigators to research resources at reduced costs; providing training and consultation with respect to equipment and technologies; and promoting or developing new technologies. The Centers support different types of research cores, including highly specialized, unique cores that focus on NIDDK research areas. They also buy into general institutional cores to provide access for Center members. The NIDDK was made aware of some perceptions in the scientific community that core access may sometimes be limited to a small number of laboratories. There was general support for broadening access to cores.

Recommendations: The NIDDK is looking at several different ways to broaden access to cores, such as using business models (see Discussion Topic 4), and using the web to advertise the availability of core resources. Other actions under consideration include: (1) possibly modifying Funding Opportunity Announcements to emphasize that broad access to cores is important, and (2) possibly providing resources to further that objective. Another possibility is to remain alert to emerging circumstances in which exceptional opportunities may arise to support small centers that would provide highly specialized expertise and services particularly useful to the broad research community (see Discussion Topic 5).

Discussion Topic 4: Core Business Models:
Findings: The NIDDK found few defined business models among the Centers. Many of the cores use a charge-back business mechanism, but different types of cores may require other business models. The NIDDK observed a lack of standard approaches in the data reported on core usage, which can present challenges for the NIDDK and for peer reviewers in making comparative assessments of Centers. Concerns were raised regarding NIDDK guidelines for some Centers that limit equipment purchase to one time per funding cycle.
Recommendations: The NIDDK will not mandate that cores use any particular business model. Instead, the NIDDK plans to develop information on core business models to disseminate to the Centers. The NIDDK is also considering the development of guidelines for collecting data on core usage. The Institute is having internal discussions about ways to harmonize principles and practices for equipment purchases to provide greater flexibility.

Discussion Topic 5. Potential Value of More Small Centers:
Findings: There was a wide range of perspectives on this topic regarding the effectiveness and efficiency that might be associated with smaller centers. Institutions that already have established centers typically found greater value in larger centers and recommended that the NIDDK broaden access to existing cores rather launch smaller, specialized Centers. Smaller institutions tended to favor smaller Centers and recommended that the NIDDK fund such Centers as highly specialized or national resources for the broad research community.
Recommendations: The NIDDK considers the advisability of launching new, smaller Centers an open question. The Institute does not currently plan to expand its Research Centers Program, but will be cognizant of emerging opportunities that might warrant the establishment of a particularly valuable small Center. This topic will remain under active discussion.

Discussion Topic 6: Center Membership:
Findings: The NIDDK found different approaches to and perspectives on Center membership. A Center's members were typically from the local (home) institution, but sometimes also from external institutions. There were different definitions of membership, as well as different categories, such as full and associate members. Sometimes, membership was a requirement for using a research core. Also, because of related research interests, some Principal Investigators were members of more than one Center--such as the Nutrition-Obesity Research Centers and the Diabetes Centers. These differences in approaches to membership can make it difficult for the NIDDK and for peer reviewers to compare the institutional base of Centers. Perspectives on Center membership varied considerably. One perspective was that membership should be inclusive to attract talented investigators to move the science forward. Another perspective was that membership numbers could be inflated if

Centers count investigators who are more peripherally involved, such as those who attend seminars but are not otherwise engaged in Center activities.
Recommendations: The NIDDK is developing a best practices document on Center membership to share with the Centers. Additionally, the NIDDK plans to establish requirements for Center membership; to clarify who may be included in the "user base" of a Center; and to outline who may use core resources. Such standard definitions are expected to enable the NIDDK to assess more accurately who is benefiting from Center resources, such as enrichment programs, and also, to enable peer reviewers to compare applications in the review process.

Changes Already Implemented and Next Steps

Dr. Germino reported on some changes the NIDDK has already undertaken. For example, the Institute has modified the Centers' guidelines for reporting the research base. For Nutrition-Obesity Research Centers and for Diabetes Centers, the NIDDK has asked investigators to list on their applications whether they are members of another Center. The Institute has modified some Diabetes Centers to promote regional and national resources. Some approaches have been taken to enhance access to Center core resources, and to promote expansion of information-sharing through the development of the Centers' web sites. The NIDDK is also revamping its own web site.

NIDDK staff members are meeting on a regular basis to develop implementation strategies for the recommendations in the report, with subgroups focused on each discussion topic. Best practices documents are being developed to address Pilot and Feasibility programs, core business models, and Center membership. Work is continuing on redesigning the NIDDK web site to highlight the Research Centers Program. As the NIDDK moves forward to strengthen its Centers Program, it seeks the Council's continuing discussion and input on the following issues:

Enhancing Synergy and Center Value: Should the NIDDK consider some measure of synergy when making funding decisions? How can the NIDDK promote Center interactions with Clinical and Translational Science Awards and other NIDDK programs? How can the NIDDK further enhance opportunities for training?

Strengthening the P&F Programs: How should the NIDDK balance support for high-risk/high-reward projects relative to support for research career development? Should the NIDDK promote the opening up of the P&F programs to extra-institutional investigators?

Core Support and Access: Should the NIDDK aim to broaden core access and continue to support both general and specialized cores? Should the NIDDK increase data collection on core usage so that reviewers can make informed decisions about how cores are or are not being utilized by the community?

Center Membership: How can the NIDDK evaluate meaningful participation of Center members without overburdening the Centers administratively?
Dr. Germino closed by expressing the Institute's appreciation for all the work that Centers performed to prepare for the sites visits, for the very thoughtful input that was submitted by

all parties during the two comment periods, and for the many contributions of NIDDK staff members.

Council Questions and Discussion

Several Council members commended the NIDDK for the thoughtful, diligent and constructive Program Review. Specific comments of individual Council members included the following:

Enhancing Synergy and Center Value: This topic engendered many comments:

- *Centers are inherently constructs for synergy and should be assessed in those terms. The synergy expected from Centers is the very reason this award mechanism exists; otherwise, the Center funds could be used for R01 grants.*
- *Synergy probably can't be mandated; however, the experiences gained during the NIDDK Program Review demonstrate that it is possible to create opportunities for potential synergies to be recognized and pursued. The key is to bring people with mutual interests together in the same room.*
- *Synergy can come from fostering interactions among NIDDK-funded Centers within and beyond the home institution, without any regional restrictions.*
- *The recognition and elimination of barriers or burdensome impediments can facilitate synergy. For example, indirect costs procedures can hinder synergistic core use by investigators external to the home institution.*
- *Synergy can be furthered by exploiting opportunities for repositories, both virtual and real, and the development and promotion of relational databases that could link clinical information and outcomes with molecular information. It is possible that synergies may emerge from the "big data" that are being generated by some research cores.*
- *Center infrastructure can be used to focus synergistically on key areas within the NIDDK research mission and to help develop investigators.*
- *Synergistic efforts can be measured not only in terms of enrichment programs and the nurturing of new investigators, but also in the development of platforms for facilitating new types of interdisciplinary grants through existing collaborative mechanisms.*
- *The value of and need for synergy could be stated very transparently in Requests for Applications, incorporated into the peer review process, and highlighted in various reports. Synergy could be given a quantitative metric in the review process, perhaps under the administrative cores.*
- *If an institution has both a Research Center and a Clinical and Translational Science Award, it should be mandatory that a plan exists or would be developed for interaction between them. Letters from the two Directors would be one mechanism.*
- *The Centers Program could exploit opportunities to demonstrate mentorship activities with respect to advisory committees, workshops, and seminars. Such activities can be concretely linked to existing NIDDK efforts across a continuum of research training and research career awards.*

Pilot and Feasibility Programs:
These programs are widely considered to be excellent. Compelling arguments can be made for using P&F funds for various types of activities; therefore, difficult choices must be made. P&F programs can be particularly helpful for junior investigators, and they can produce a high return on investment. It would be helpful to track the use of P&F funds at individual

Centers and across the entire Program with respect to the number of pilot awards that have stimulated R01 grants, and perhaps even promoted a more rapid attainment of such grants than otherwise would have occurred.

Council members offered somewhat different thoughts on the use of P&F funds for high-risk/high-reward research. One view is that junior investigators are generally considered to be inherently engaged in such research; therefore, enhancing their support would further that type of research. Another view is that too much emphasis should not be placed on Centers for conducting high-risk/high-reward research. Rather, Centers should collaborate with other programs at their home institutions to generate additional funds for such research.

Council members also expressed somewhat different views as to whether the P&F programs should be opened up to investigators beyond a Center's home institution. One view is that the P&F programs are already highly competitive and therefore the addition of applicants external to the home institution is not necessary to enhance the competitive process. Another view is that the P&F programs should be accessible to external investigators when possible, but the P&F programs must remain focused on the best science and tilt toward new investigators. A third view is that it may be advisable to include some extra-institutional investigators in P&F programs, provided that they have specific or niche expertise that would bring a new scientific dimension or component to the programs.

Core Support and Access: *Broadened core access and support are viewed as desirable, both for the general cores, such as transgenic and sequencing facilities, and for the specialized cores. Certain centralized resources, such as high-throughput sequencing, would not exist at some institutions without a Research Center that has such a core. There has been a lack of development and expansion of niche cores that could serve the national research community.*

Business Models and Data Collection: *Research Centers that have a charge-back system for services, such as the use of research cores, basically have a built-in accounting system for recording the users of resources and the frequency of use.*

Membership: *Membership can be a huge issue when an institution is applying or reapplying for Center funding because it is an indicator of scientific strength. The current system for determining membership can be parochial; moreover, it can be an administrative burden if all core usage must be documented. While some components of the current system should be maintained, the determination of membership should have some plasticity in criteria with respect to measuring the contributions of Center membership both intellectually and scientifically. An investigator's record of grants and publications can be an appropriate criterion for Center membership because it points to scientific productivity.*

Best Practices: *Sharing best practices would be very useful--in printed form, on-line, and through meetings. The Centers Program might also consider modeling the ways that the Department of Veterans Affairs assists investigators in developing successful applications for conducting clinical trials.*

VIII. COUNCIL FORUM: "Big Data--What Is It and How Does It Affect NIDDK? Challenges and Opportunities"

Dr. Rodgers introduced the Council Forum by noting that the biomedical research community is using more data-intensive technologies as a means to accomplish activities that range from achieving major discoveries in basic science to identifying important associations between information items contained in clinical data repositories or electronic medical files. The indexing, storage, analysis, and sharing of these data--and the insights derived from the data--are becoming increasingly important.

A. "Overview of Big Data"

Dr. Ron Margolis, Senior Advisor, Molecular Endocrinology, and Associate Director for Grants Administration within the Division of Diabetes, Endocrinology, and Metabolic Diseases

Dr. Margolis said that big data is loosely defined as datasets that are so large and complex that available tools are not capable of dealing with functions such as data capture, storage, searching, analysis, condensing, visualization, and communication. Important nuggets of information may be embedded in massive data sets, but if they cannot be extracted, analyzed, presented graphically, and transmitted to others, they have no utility. Some major sources of big data include the physical sciences, consumer data, and social media. In the biomedical sciences, there are enormous amounts of data generated from chemical biology and clinical investigations. For the NIDDK's purposes, big data can be considered the data that result from studies that seek to understand biological processes through data-intensive techniques. Dr. Margolis noted that the meaning of "big" keeps expanding--from kilobytes, to megabytes, to gigabytes, to terabytes, to petabytes, and beyond. Current Internet transmission speed is optimally about ten megabytes per second, but the next iteration of the Internet will feature speeds that may be 100 megabytes per second.

Dr. Margolis gave several examples of governmental efforts to address the challenges of big data. In Fiscal Year 2012, the federal government began a $200 million Big Data Research and Development Initiative that reached across all agencies. The purpose is to develop government-wide frameworks and goals regarding the collection, use, and transparency of big data, and ways to enhance its value. This initiative also supported future needs assessment. The National Science Foundation has a $20 million program, to which the NIH has contributed, on "Core Technologies for Advancing Big Data Science and Engineering." The NIH Advisory Committee to the Director (ACD) has a Data and Informatics Working Group, which submitted a June 2012 report. There is also a trans-NIH Big Data Working Group, through which NIH staff will follow-up on and implement the ACD Working Group's recommendations. The NIDDK supports dkCOIN, the NIDDK Consortium Interconnectivity Network.

Dr. Margolis elaborated on the way that dkCOIN serves the needs of basic and clinical investigators by providing seamless access to large pools of data relevant to the Institute's mission. The goal is to develop a community-based network for integration across disciplines to include the larger NIDDK universe of diseases, investigators, and potential users. The Institute has a strong interest in big data because NIDDK-funded investigators are using data-intensive technologies to accumulate such data through NIDDK basic science consortia, R01 and Research Center grants, and clinical trials. Refining ways to mine these data may help to

identify otherwise unseen trends and relationships that can provide new insights regarding diseases within the NIDDK mission. Another potential benefit of data mining would be reductions in redundancy and duplication of effort. To this end, there is a need for a bioinformatics ecosystem that encompasses all the tools necessary to derive the greatest value from the data that are being accumulated.

B. "Secondary Use of Health Care Big Data for Translational Research"
Dr. Shawn Murphy, Medical Director of Research Computing and Informatics, Partners HealthCare; Associate Professor of Neurology at Harvard Medical School; and Associate Director of the Laboratory of Computer Science at the Massachusetts General Hospital

Dr. Rodgers introduced Dr. Shawn Murphy, who developed and currently directs the Research Patient Data Registry (RPDR) for Partners HealthCare. The RPDR is a large data warehouse with data on six million patients and about 1.6 billion rows of clinical data; it serves as a central clinical data registry for inpatient and outpatient encounters in order to support clinical research. Dr. Murphy is also Principal Investigator for software development for the NIH-sponsored Informatics for Integrating Biology and the Bedside (i2b2) Center. This Center is an open-source project that integrates data from the hospital medical record and the bioinformatics community into a common software platform, with over 70 operating installations worldwide. Dr. Murphy holds a Ph.D. in Pharmacology from the University of Chicago and an M.D. from the Pritzker School of Medicine at the University of Chicago. His earlier career path includes an internship in internal medicine at Beth Israel in Boston, a neurology residency at the Massachusetts General Hospital (MGH), and fellowships in epilepsy and computer science at MGH.

Dr. Murphy's presentation centered on the ways that big data are being mined and managed to advance clinical and translational research. His main focus was the work conducted by the Informatics for Integrating Biology and the Bedside (i2b2) Center. (https://www.i2b2.org/) This open-source Center is an NIH-funded National Center for Biomedical Computing (NCBC). It is based at Partners HealthCare in Boston, Massachusetts, a not-for-profit, integrated health care system comprised of medical and research institutions. (http://www.partners.org/) Dr. Murphy acknowledged the enormous number of individuals who have made i2b2 possible.

According to Dr. Murphy, the directors of research enterprises and the community of scientific investigators want to know more about big data because it can be very useful in facilitating clinical trials; helping to identify some of the correlates of common diseases and health problems; furthering hypothesis-driven research; and speeding the translation of findings into medical practice. For example, mining big data can be important for understanding the relationships between genetic and genomic information. The data can shed light on the connections between the presence of certain genes (genotypes) and their expression in disease states (phenotypes). Considerable resources are needed to link the big data that are emerging from studies that use high-throughput genotyping and high-throughput phenotyping techniques.

Mining and managing big data are complicated tasks because the data are not only vast, but also, often intertwined. The challenges include: (1) querying the data to find meaningful nuggets while sifting through piles of information that are not particularly useful; (2) making

privacy-related deletions in highly intricate, interwoven big data; and (3) sharing data--both the big data itself, and the metadata that synthesize important data points and elucidate the data's meaning.

With regard to clinical studies and trials, Dr. Murphy described the role that the i2b2 Center plays in helping investigators query (search) big data in order to identify patients for inclusion in research protocols--in accordance with legal requirements to protect the privacy of patients. Under the Health Insurance Portability and Accountability Act (HIPPA), all patients at Partners HealthCare are notified upon registration that their data may be used for research. Dr. Murphy described three major components of the data query and retrieval process. First, an authorized investigator uses an i2b2 query to determine if there is a sufficient number of patients, in the aggregate, without personal identifiers, who have a disease or condition he or she plans to study. Second, to determine if those patients would be eligible to participate in the research protocol, the investigator must obtain approval for the planned research from an Institutional Review Board in order to conduct additional queries for more specific information. The investigator then explores phenotypes of these patients using i2b2 tools and a translational team of experts, which has been developed specifically to work with medical record data. The detailed information sought may include coded diagnoses, laboratory findings, physical findings, medical procedures performed, and genomic data. In the third step of the process, the i2b2 Center provides refined, detailed data and related reports to the investigator in an organized fashion, noting the different sources of and codes for the data. The Center also provides images, which can be critically important in characterizing the phenotypes of patients. Dr. Murphy noted that there are legal controls on certain types of data, including genomic data. For example, information resulting from non-diagnostic screening tests for the presence of genes cannot be used for research purposes.

By displaying and using an interactive query form, Dr. Murphy demonstrated the way that queries can be constructed and run. Depending on the formulation of a query, it is possible to identify patients who have either a single disease or multiple diseases. In a similar fashion, it is possible to search on combinations of patient characteristics and genes, and also, to identify matched controls. When an investigator submits a query, it is run against approximately 1.5 billion observations about patients. About 3,000 investigators are using these data-mining approaches, which are helping to further many millions of dollars in research activity.
In addition to aiding patient recruitment for clinical trials, a major goal of the i2b2 Center is to perform certain types of clinical and translational studies via computers--*"in silico."* For example, using the i2b2 system, researchers were able to see that the occurrence of myocardial infarction was statistically high in diabetes patients who were treated with a specific medication. This finding has informed medical practice. The ability to identify these types of interrelationships may enable the development of "virtual" clinical trials that will assess existing, well-organized patient data retrospectively, thereby avoiding the high costs of prospective trials.

Dr. Murphy described many highly technical aspects of the architecture and operations of the i2b2 system. He noted that original data are retained at the location where the information is initially generated--surrounded by firewalls and other protections. Through the use of carefully constructed indexes, the i2b2 software can cross institutional boundaries to access that data, and extract, store, and analyze the components that are needed for research purposes. While the i2b2 Center can efficiently search the medical records of millions of

patients, Dr. Murphy emphasized that the indexing, culling, refining and interpretation of data are challenging. For example, defining the types of rheumatoid arthritis patients sought for a clinical trial may involve construction of a phenotypic definition involving several codes, as well as the patient's previous medical treatments and test results. So-called "smart" technologies enable the i2b2 Center to drill down into massive amounts of data to find such specific information. To understand and code a physician's short-hand-like notations on a medical record, i2b2 scientists use an approach called "natural language processing." Importantly, the i2b2 Center uses different ways to verify information, including the use of human experts to review the data, often in graphic form, to see if the data make sense.

Dr. Murphy commented positively on the NIDDK Consortium Interconnectivity Network--dkCOIN. (www.dkCOIN.org/). He pointed out some of the dkCOIN attributes relative to the i2b2 system. Both i2b2 and dkCOIN use ontologies (logically constructed classes, attributes, relationships, etc.) to represent and query the data; they have data connected around a basic unit in a modular fashion; and they have uniform points of access. While i2b2 and dkCOIN share these and other similarities, their fundamental approaches to indexing and querying are quite different. Specifically, the central unit in the i2b2 approach is the patient--with attendant privacy concerns--whereas the central unit in dkCOIN is the gene. In Dr. Murphy's view, the data in the health sciences are largely being indexed in one of these ways; therefore, research investments could help to bridge these two approaches. Another difference is that i2b2 is considered a "closed world" system in which tight data control is needed; attributes such as patients' visit numbers are essential to successful data retrieval; and queries are confined to running against an established database. In contrast, dkCOIN represents an "open-world" system, in which queries, which are similar in approach to web-based searches, can link many attributes together and evolve in different directions beyond a single data source. Dr. Murphy said that researchers will select the most appropriate systems to use depending upon the questions they seek to answer.

In closing, Dr. Murphy noted some of the recommendations of the Data and Informatics Working Group of the Advisory Committee to the Director (ACD), NIH. (http://acd.od.nih.gov/diwg.htm) The recommendations address a range of issues such as sharing data across institutional boundaries, developing and maintaining software tools, furthering workforce development, and increasing the speed of data transmission.

Council Questions and Discussion

Leveraging Investments in Big Data Resources:

- *It is important to leverage the outstanding resources of the i2b2 Center, which is moving forward based on important principles. While still evolving, it is a worthwhile undertaking, which can promote synergy across centers and institutions.*
- *The theory of ownership is receding in science as the value of collaboration is increasingly recognized, especially in the field of genetics. The use of concrete, commonly understood terminology would facilitate that process.*
- *It would be helpful to embed computer experts and analysts within research projects along with biomedical scientists, especially geneticists.*
- *Because publishing in scientific journals is a natural way scientists think about data and research results, it should be a central principle for broad dissemination of large data sets, including those from Genome-Wide Association Studies (GWAS).*

- *As mechanisms for handling big data develop further, issues of privacy and intellectual property will continue to be significant and must be addressed.*

Comparing Different Systems: *What is being done to translate data between i2b2 and some of the commercially available systems for maintaining electronic medical records (EMRs)?* Dr. Murphy responded that commercial databases are largely transactional systems in which the rapid turn-around of data may be needed in a hospital setting. In contrast, i2b2 is an analytical system intended to facilitate research, and it is usually updated only once a day.

Answering Mission-Oriented Questions: *The NIDDK should harness informatics and related technologies to answer the questions that are central to the Institute's research mission. The NIDDK could incentivize scientists to use computational technologies to move gene-expression research forward into clinically oriented studies, which could lead to the development of new therapies.*

Stakeholders, Users and Trainees:

- *Practically everyone who is studying biological processes has a stake in big data and should be using or learning to use the very powerful computational tools that now exist. Systems for handling big data should be user-friendly to post-doctoral and graduate students in the laboratory.*
- *The NIDDK could create a whole group of new clinical investigators by making available the tools to use big data. The Institute could enhance the computational training of researchers in sub-specialty fields within its research mission.*
- *Students of modern molecular biology show a remarkable ability to learn the skills necessary to analyze and manipulate large data sets. The NIDDK should encourage and incentivize that type of knowledge acquisition through existing funding mechanisms. For example, NIDDK Research Centers that are generating high-throughput data in core facilities could train experimental scientists to analyze and discuss their own data at a sophisticated level.*
- *It is important to encourage training in computational biology for individuals who have superior mathematical skills. If the NIDDK can create an intellectual home for these individuals by providing training opportunities, the Institute could create an incredibly powerful human resource for mining large data bases and for developing the next generation of analytic tools.*
- *Academia has a role to play in terms of providing promotion and tenure opportunities to highly talented individuals who are working with big data.*
- *The promise for research advances in this area is huge because big data can provide unbiased ways to reveal important associations that can yield biological and medical insights, and that can help to generate new hypotheses about diseases.*

Quality of Data: *Until more standardized ways are developed to encode and refine data, concerns will exist that the conclusions based on the data are not robust. Also, the fact that human beings still need to interpret some data underscores the need for an effective human/computer interface.*

IX. SCIENTIFIC PRESENTATION: "From Genes to Therapies: Platelets at the Center of the Universe"

Dr. Kenneth Kaushansky, Dean of the School of Medicine and Senior Vice President of the Health Sciences for Stony Brook University

A leading hematologist and Member of the Institute of Medicine, Dr. Kaushansky has conducted seminal research on the molecular biology of blood cell production. His team has cloned several of the genes important in the growth and differentiation of blood cells. An accomplished clinician, he has been a champion of training more physician-scientists to further the translation of research discoveries into improved treatments and technologies for the prevention, diagnosis and management of disease.

X. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1477 grant applications, requesting support of $406,930,762 were reviewed for consideration at the September 12, 2012 meeting. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, and additional 1109 applications requesting $365,366,575 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the September 12, 2012 meeting.

XI. ADJOURNMENT

Dr. Rodgers

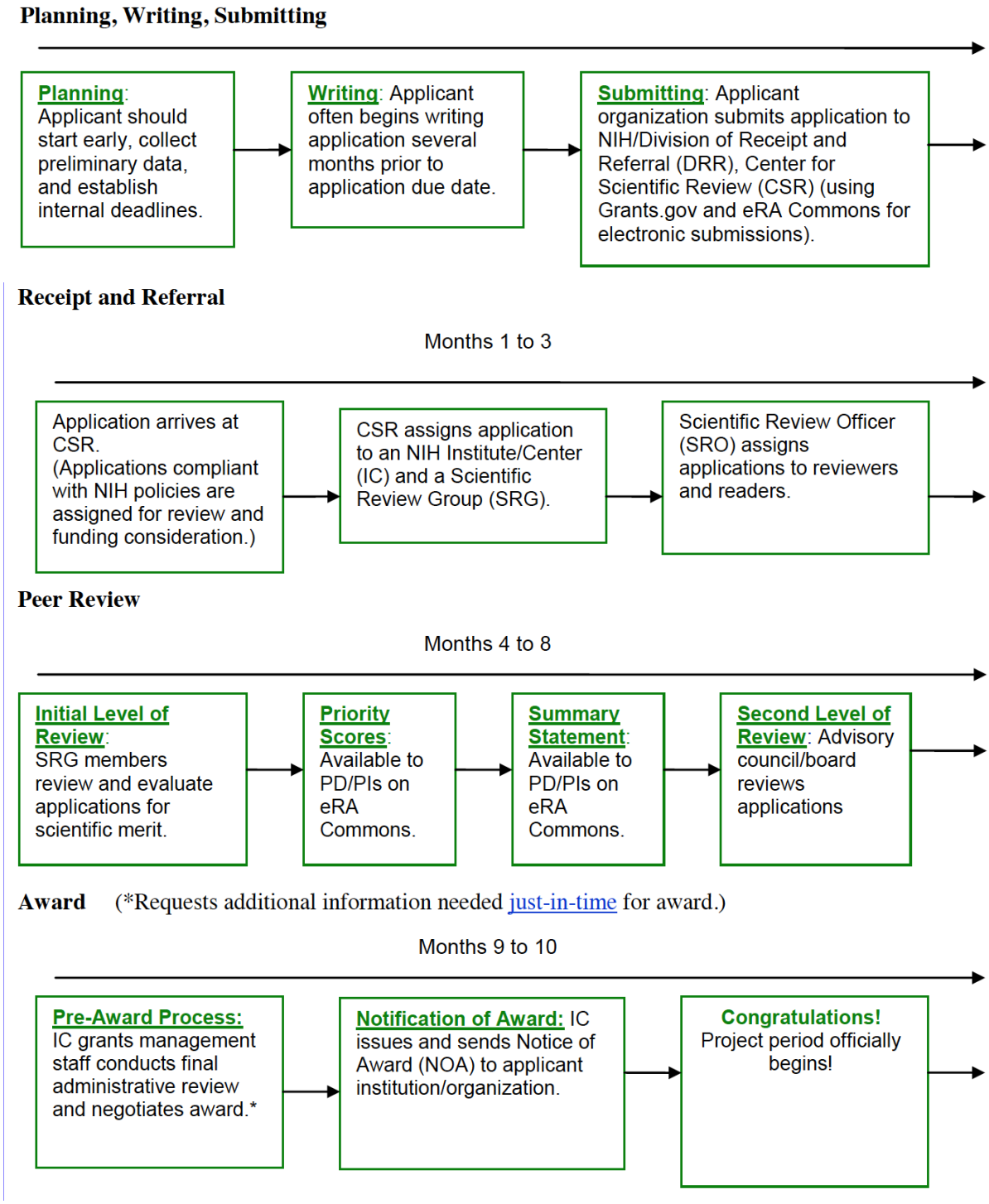
Dr. Rodgers expressed appreciation to all the presenters and discussants. He thanked the Council members for their attendance and valuable input. There being no other business, the 190th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m., September 12, 2012.

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

Grants Process At-A-Glance

The following NIH "Grants Process At-A-Glance" chart is provided as a sample of the general time element necessary for a competing application to proceed from Receipt and Referral through the Peer Review process to negotiation and award.

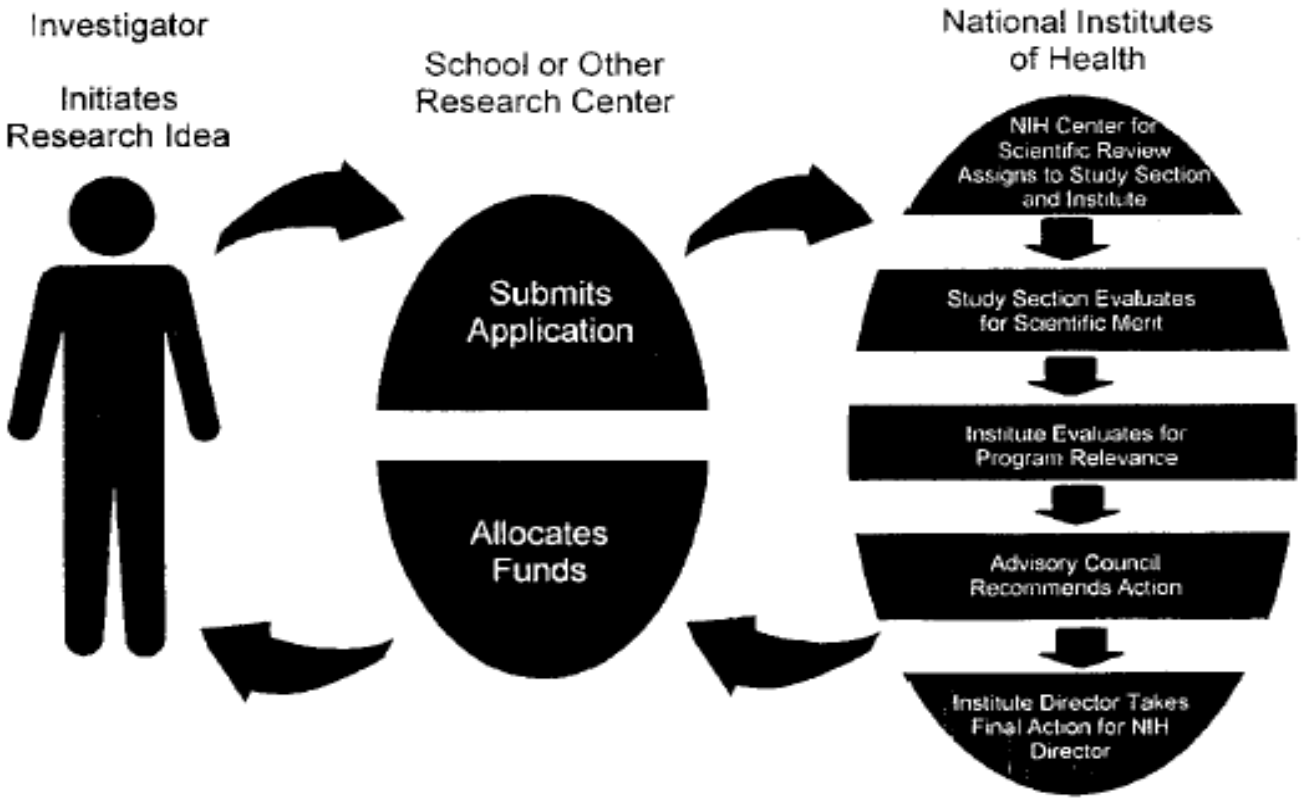


Post-Award Management

Administrative and fiscal monitoring, reporting, and compliance.

Note: Timeline is based on the standard grants process. It does not reflect a shorter timeframe for grants undergoing expedited review.

Review Process From Application to Award



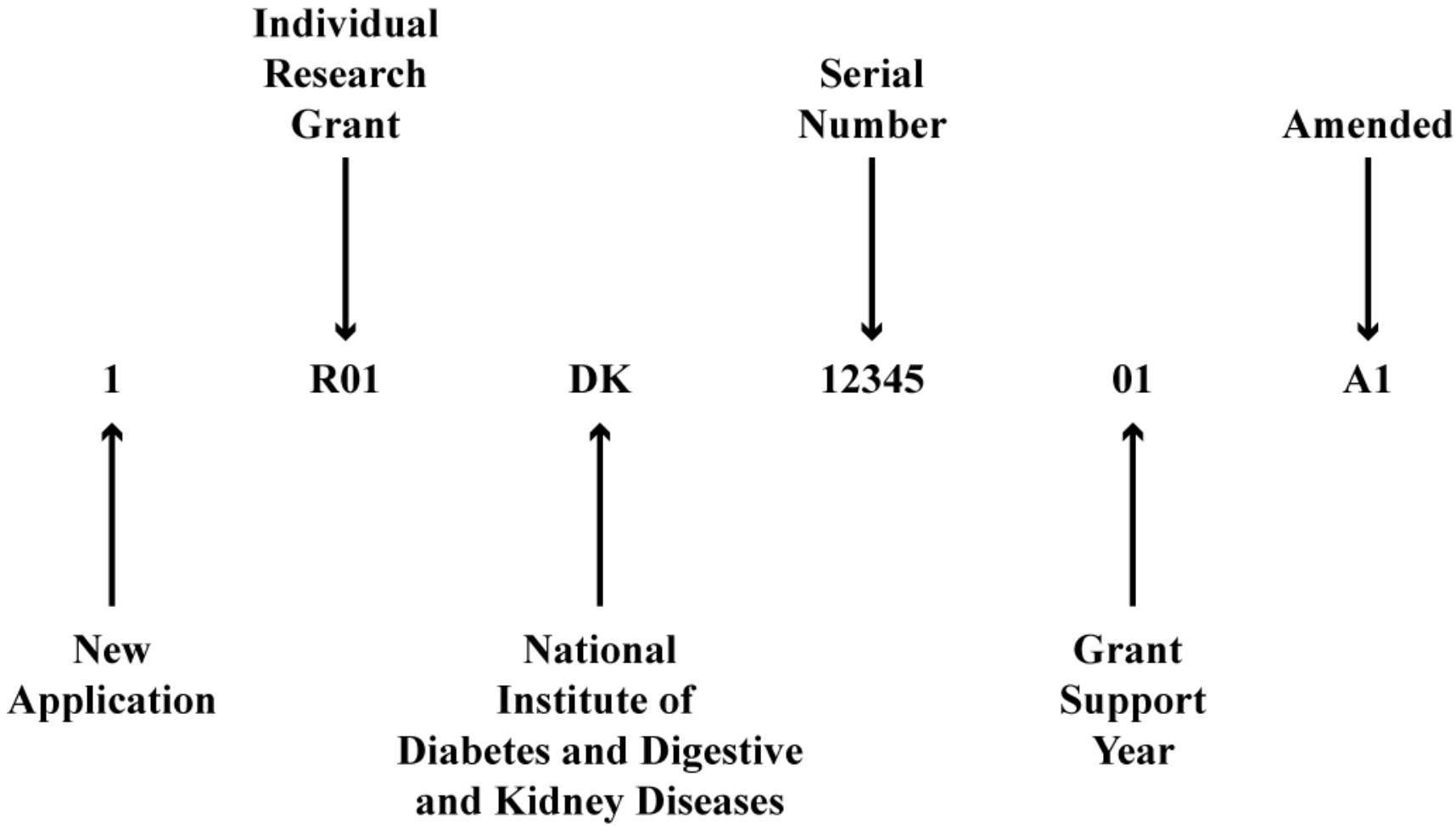
NIH Grant Receipt, Review, and Award Schedule

Jan-May **May-Sept** **Sept-Jan**	**Receipt Dates**
June-July **Oct-Nov** **Feb-Mar**	**Review Dates**
Sept-Oct **Jan-Feb** **May-June**	**National Advisory Council/Board Dates**
Dec1 **Apr 1** **July 1**	**Earliest Possible Beginning Date**

NIH Funding Instruments

Grant (NIH as Patron)	Cooperative Agreement (NIH as Partner)	Contract (NIH as Purchaser)
Project Conceived by Investigator	Project Conceived by Investigator or NIH	Project Conceived by NIH
NIH Supports or Assists	NIH Supports or Assists	NIH Acquires Services or Product
Performer Discusses Details and Retains Scientific Control	NIH Participates in Direction	NIH Exercises Direction and Control
NIH Maintains Cognizance	NIH Monitors	NIH Closely Monitors
Accomplishes a Public Purpose	Accomplishes a Public Purpose	For the Direct Benefit of the Government

Sample Application Number

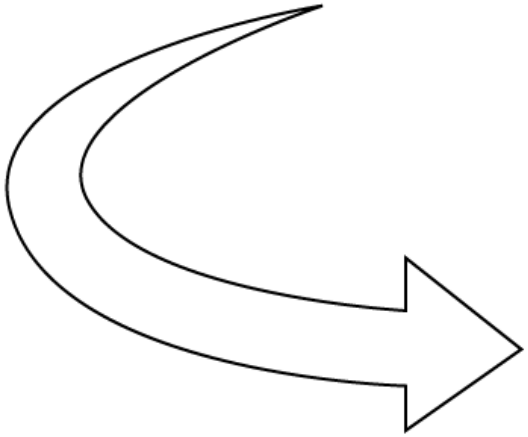


Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award



Second Level of Review

Council

- Assesses quality of SRG Review of Grant Applications *(See Advisory Council Voting Options)*
- Makes Recommendations to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Second Level of Review: Advisory Council Voting Options

- Concurrence with study section action
- Modification of study section action
- Deferral for re-review

NIDDK Makes Funding Decisions Based on:

- Scientific merit
- Program considerations
- Availability of funds

Initial Review Process

Overview

NIH policy is intended to ensure that grant applications submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects."

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding.

First Level of Review

Initial peer review meetings are administered by either the Center for Scientific Review (CSR) or another NIH IC. The focus of review is specified in the Funding Opportunity Announcement. Peer review meetings are announced in the Federal Register. The meetings are closed to the public, although some meetings may have an open session; the Federal Register provides the details of each meeting.

A. Peer Review Roles and Meeting Overview

Scientific Review Officer:

Each SRG is led by a Scientific Review Officer (SRO), formerly Scientific Review Administrator (SRA)]. The SRO is an extramural staff scientist and the Designated Federal Official responsible for ensuring that each application receives an objective and fair initial peer review, and that all applicable laws, regulations, and policies are followed.

SROs:

- Analyze the content of each application, and check for completeness.
- Document and manage conflicts of interest. See NOT-OD-11-120 issued on September 26, 2011, and briefly described at end of this chapter.
- Recruit qualified reviewers based on scientific and technical qualifications and other considerations, including:
    - Authority in their scientific field (42 CFR 52h.4)
    - Dedication to high quality, fair, and objective reviews
    - Ability to work collegially in a group setting
    - Experience in research grant review
    - Balanced representation
- Assign applications to reviewers for critique preparation and assignment of individual criterion scores.
- Attend and oversee administrative and regulatory aspects of peer review meetings.
- Prepare summary statements for all applications reviewed.

SRG Members

Chair:

- Serves as moderator of the discussion of scientific and technical merit of the applications under review.
- Is also a peer reviewer for the meeting.

Reviewers:

- Declare Conflicts of Interest (COI) with specific applications following NIH guidance. (See COI section below.)
- Receive access to the grant applications approximately six weeks prior to the peer review meeting.
- Prepare a written critique (using Review Critique Fill-able Templates) for each application assigned per the SRO, based on review criteria and judgment of merit.
- Assign a numerical score to each review criterion
- Make recommendations concerning the scientific and technical merit of applications under review, in the form of final written comments and numerical scores.
- Make recommendations concerning protections for human subjects; inclusion of women, minorities, and children in clinical research; welfare of vertebrate animals; and other areas as applicable for the application (see guidance for reviewers on Human Subjects Protection and Inclusion, Human Embryonic Stem Cells, and Vertebrate Animals).
- Make recommendations concerning appropriateness of budget requests (see Budget Information for Reviewers).

Other NIH Staff:

- Federal officials who have need-to-know or pertinent related responsibilities are permitted to attend closed review meetings.
- NIH IC or other federal staff members wishing to attend an SRG meeting must have advance approval from the responsible SRO. These individuals may provide programmatic or grants management input at the SRO's discretion.

Peer Review Meeting Procedures

- Applications are reviewed based on established review criteria (see below).
- Assigned reviewers summarize their prepared critiques for the group.
- An open discussion follows.
- Final scoring of overall impact/priority scores is conducted by private ballot.

B. Peer Review Criteria and Considerations

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Review Criteria for Research Grants and Cooperative Agreements

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria. Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects
Inclusion of Women, Minorities, and Children
Vertebrate Animals
Biohazards
Resubmission
Renewal
Revision

Additional Review Considerations. As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Select Agent
Resource Sharing Plans
Budget and Period Support

C. Scoring

The scoring system described below was implemented for applications submitted for funding consideration for FY2010 and thereafter (NOT-OD-09-024)

Before the SRG meeting, each reviewer and discussant assigned to an application will give a separate score for each of five review criteria (i.e., Significance, Investigator(s), Innovation, Approach, and Environment for research grants and cooperative agreements; see above). For all applications, even those not discussed by the full committee, the individual scores of the assigned reviewers and discussant(s) for these criteria are reported to the applicant.

In addition, each reviewer and discussant assigned to an application gives a preliminary overall impact/priority score for that application. The preliminary scores are used to determine which applications will be discussed in full. For each application that is discussed at the meeting, a final impact/priority score is given by each eligible committee member (without conflicts of interest) including the assigned reviewers. Each member's score reflects his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than being a calculation of the reviewer's scores for each criterion.

The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact/priority score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores, and multiplying the average by 10; the final overall impact/priority score is reported on the summary statement. Thus, the final overall impact/priority scores range from 10 (high impact) through 90 (low impact). Numerical impact/priority scores are not reported for applications that are not discussed (ND), which may be reported as *.* on the face page of the summary statement and typically rank in the bottom half of the applications.

Applicants should contact the Program Officer for the application to seek additional feedback on the score and summary statement.

An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

The following guidance has been given to reviewers to determine individual review criterion and overall impact/priority scores:

High Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
Medium Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
Low Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

D. Summary Statement

Applications that are not discussed at the meeting will be given the designation “ND” as an overall impact/priority score, but the applicant, as well as NIH staff, will see the scores from the assigned reviewers and discussants for each of the review criteria as additional feedback on their summary statement.

Understanding the Percentile

- A percentile is the approximate percentage of applications that received a better overall impact/priority score from the study section during the past year.
- All percentiles are reported as whole numbers
- Only a subset of all applications receive percentiles. Which types of applications are percentiled varies across different NIH Institutes and Centers.
- The summary statement will identify the base that was used to determine the percentile.

E. Appeals

To preserve and underscore the fairness of the NIH peer review process, NIH established a peer review appeal system (see NIH Guide Notice NOT-OD-11-064) to provide investigators and applicant organizations the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was flawed as outlined below. The appeals policy applies to appeal letters received with respect to the initial peer review of all competing applications submitted to the NIH for support for the January 25, 2011 due date and thereafter, including: 1) reviews conducted by the NIH Center for Scientific Review (CSR) and reviews conducted by the NIH Institutes and other NIH Centers; and 2) applications such as fellowship application that typically do not require Council review. This policy does not apply to appeals of the technical evaluation of R&D contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT award.

An appeal is a written communication from a Project Director/Principal Investigator (PD/PI) and/or official of the applicant institution [not necessarily the Authorized Organization Representative (AOR)] that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence of the AOR. An appeal letter will be accepted only if the letter 1) describes a flaw(s) or perceived flaw(s) in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers
- Conflict of interest, as specified in regulation at 42 CFR 52h "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-federal peer reviewers
- Lack of appropriate expertise within the SRG
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

The IC cannot deny the PD/PI and/or the applicant institution the opportunity to have an appeal letter made available to Council, but the IC may determine which appeal letters warrant discussion by the Council members, and Council members may raise certain ones for discussion if they so choose. The Council may concur:

- with the appeal, and recommend that the application be re-reviewed.
- with the SRG's recommendation and deny the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

Information from http://grants.nih.gov/grants/peer_review_process.htm.

F. Revised Conflict of Interest Policy for Initial Review

The NIH initial peer review process involves the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to the National Institutes of Health (NIH). The process, defined in regulation at 42 CFR Part 52h, is extended by policy to other types of applications submitted to the agency.

On September 26, 2011, the NIH issued a revised policy on managing conflict of interest (COI) in the initial peer review of NIH grant and cooperative agreement applications: see NOT-OD-11-120. This announcement provides revised policy for managing COI, the appearance of COI, prejudice, bias, or predisposition in the NIH initial peer review process.

The announcement addresses multi-disciplinary and collaborative research and clarifies the role of non-Federal and Federal employees serving as reviewers. Unlike members of NIH Advisory Councils or Boards, reviewers in the initial level of NIH peer review are not appointed as Special Government Employees and do not submit financial disclosure forms. Therefore, SROs are not in a position to collect financial information from reviewers, but can ask about professional relationships and roles as defined in the revised NIH policy and make determinations about potential bias in the initial peer review process.

The overall goal of the revised policy is to increase transparency and to inform the scientific community. With the dramatic increase in internet capability, reviewers may be looking up financial information about investigators on the websites of the investigators' institutions. Although this COI information is available publicly, SROs should instruct reviewers not to consider COI information about applicants in their reviews, discussions, or evaluations.

Similarly, applicants may be looking up financial information about reviewers on their institutions' websites and submitting appeals of initial peer review on the basis of that information. Therefore, it is important that SROs clearly explain the conflict rules for initial peer review to their reviewers.

Second-Level Review Procedures

The Advisory Council/Board of the potential awarding Institute or Center (IC) performs the second level of review. Advisory Councils/Boards are composed of scientists from the extramural research community and public representatives (NIH Federal Advisory Committee Information). Members are chosen by the respective IC and are approved by the Department of Health and Human Services. For certain committees, members are appointed by the President of the United States.

On June 18, 2010, President Obama issued "Lobbyists on Agency Boards and Commissions," a memorandum directing agencies and departments in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions. On October 5, 2011, the Office of Management and Budget (OMB) issued final guidance to Executive Departments and agencies concerning the appointment of federally registered lobbyists to boards and commissions. This guidance applies not only to advisory committees subject to FACA, but to all other groups as well-even to members of working groups not appointed as SGEs. See *Federal Register* / Vol. 76, No. 193 / Wednesday, October 5, 2011/Notices under OFFICE OF MANAGEMENT AND BUDGET, Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions, AGENCY: Office of Management and Budget. ACTION: Notice of Final Guidance.

Second-level review is the assessment of the quality of the initial review of grant applications. By law, NIDDK's Advisory Council must recommend an application before the Institute can fund it. Second-level review is **not a second scientific review**. Rather, the Council looks at applications with potential barriers to funding such as human subjects and animal concerns or special circumstances such as foreign applications and renewal applications requesting more money than the limit.

The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote. When Council recommends an application for funding, that doesn't necessarily mean it will receive an award. NIDDK makes the final decision.

Applications Requiring Council Discussion

- Applications from Foreign Institutions

  In reviewing and making recommendations on foreign grant applications, the Council members should be aware that ALL of the following criteria must be met in order to be supported by the NIH:

  a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing United States resources.
  b. The project has specific relevance to the mission and objectives of NIDDK and has the potential for significantly advancing the health sciences in the United States.
  c. The application must be approved for funding by the Council.
  d. The application may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.

- Applications With Concerns about Human or Animal Subjects and/or Gender and Minority Representation

The Council will be asked to comment on any application(s) recommended for possible funding with unresolved concerns regarding the involvement of human subjects, the use of animals, and/or gender and minority representation. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern(s).

- Applications That May Not Provide for Appropriate Biosafety, Biocontainment, and Security of Select Agents

  The Council will be asked to comment on any applications recommended for possible funding with unresolved concerns regarding biosafety, biocontainment, and security of select agents. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern.

- Letters of Appeal

  The Council reviews appeal letters that were submitted by investigators subsequent to the peer review of their application and were not resolved by program and review staff. It is the responsibility of NIDDK staff to determine whether a letter is an appeal.

  An investigator may have concerns about and may wish to appeal a procedural aspect of the peer review process. Only letters concerning procedural aspects of a review are considered an appeal. Procedural issues fall under four categories and the applicant must claim one or more of the following:

  a. The initial review was biased.
  b. A conflict of interest existed.
  c. The review group lacked appropriate scientific expertise.
  d. Factual errors entered into the review.

  Differences in scientific opinion that often occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals.

  The Council has two options when reviewing an appeal letter:

  a. To concur with the outcome of the initial peer review as reflected in the summary statement.
  b. To concur with the claims discussed in the applicant's appeal letter and recommend deferral for re-review either by the same or a different review group.

  Other letters, termed Council communications, are also made available to the Council at the discretion of NIDDK staff.

Special Council Review of Research Applications from Program Directors/Principal Investigators (PDsPIs) with more than $1.0 Million Direct Costs in NIH Support

In an effort to continue responsible stewardship of public funds and to support meritorious and innovative research, NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html. Pending grants going to Council from PDs/PIs who have more than $1 million in direct costs from active NIH Research Project Grants (RPGs) grants will be subjected to additional consideration. It is important to recognize that this is a threshold only; investigators who have more research support may still receive additional awards as warranted. When making funding recommendations, staff will

take into account factors such as: how innovative and distinct the pending project is from the PD/PI's other grants; the type of research (since costs requirements differ substantially by field); the public health priority of the research; and how the absence of an award impacts other collaborative or translational research efforts.

The following SCR policy guidance is designed to achieve these goals.

- Criteria Considered by NIDDK Staff for Determining Applications Subject to SCR

    a. P01s and other Multi-Component RPGs: Only funds acquired[1] through RPGs[2] should be included when calculating a given PD/PI's support.
    b. Only competing RPGs (New and Renewals) to be considered for award to investigators with $1.0M or more of direct cost NIH support are subject to SCR via this policy.
    c. P01s and other Multi-Component RPGs:
        i. Competing Multi-Component RPGs are not subject to SCR unless all of the component leaders have $1.0M or more of NIH support. The rationale for this is that failure to support one or more of the leaders who exceed the limit could significantly detract from the project as a whole.
        ii. Funded P01s and any other multi-component RPGs, including consortium/sub-award costs, contribute to the $1.0M threshold of the Program Director and sub-project leaders. Each sub-project leader's total should include the funds provided directly to him/her only through the P01; core costs should not be included.

- Multiple PD/PI Projects:
    a. Competing Multi-PI applications are only subject to SCR if all the PD/PIs exceed the $1.0M threshold.
    b. In calculating the research support available to a PD/PI who participates in a multi-PI award, the direct cost award amount to the institution should be divided evenly among PIs at that institution. Budgets of multi-PIs at other institutions may be determined using the funds allocated to their subcontract costs.

- Requests for Applications (RFAs):
    a. Pending applications submitted in response to RFAs will not be subjected to SCR. The rationale is that these applications have been solicited by the IC to accomplish a specific purpose. The intent is to award the best proposal(s) designed to achieve the IC's specified goal(s).
    b. Funds provided through these grants will contribute to the $1.0M threshold for the investigators' future applications.

- Competing revisions and administrative supplements:
    a. These types of grants are not expected to be a significant contributing factor in reaching the threshold, since many will not incur future year commitments. However, multi-year supplements are included in grant's out-year commitments and do contribute to the $1.0M threshold. In order to prevent Re-entry and Diversity Supplements from being an impediment to an investigator, to the extent possible, these supplements should be excluded from the threshold count.

[1] Funds acquired include active RPG awards for the PD/PI (exclusive of projects in no cost extension) when the application subjected to SCR is pending Council review and funds for multi-year projects allocable to the current Fiscal Year (Multi-Yr: R15, DP2, DP3, DP4, RC3, RC4, R55, RC1)

[2] Defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

- Guidelines for Council Consideration (Council role):
  a. When applied to new projects, SCR will focus on the unique opportunities afforded to the investigator to advance his/her research in directions that are highly promising and distinct from his/her other funded projects.
  b. SCR of renewal applications may also consider the value of continuing a productive project and the contribution this project makes to the investigator's research program and ongoing collaborations.
  c. Consideration may also be given to the PD/PI's field of research when evaluating the appropriateness of awarding new grants above the $1.0M direct cost threshold. The rationales for this consideration are that 1) different types of research (e.g., clinical trials, population sciences) may require larger awards than other fields and 2) non-RPG mechanisms often used for an IC's specialized purposes/goals typically receive separate Council consideration. Since some RPGs, such as U01s, are also used for projects with specialized purposes/goals, each IC, working with its Council, may create defaults for these and other RPG mechanisms or programs to simplify SCR.

NIDDK Implementation of the Second Council Review Policy

Each Council round, the NIDDK Council members will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under the NIH policy as outlined above. During the closed session, for each application on the list that might actually be funded, NIDDK staff will provide information about the other NIH funding for the PI that brings his/her direct cost total to the $1 million threshold and a justification for possibly funding the application under consideration. Council members will review these cases and decide whether or not they have concerns.

Recommendation Process

- NIDDK program staff members examine applications, their overall impact/priority scores, percentile rankings, and their summary statements and consider these against NIDDK's needs.
- Program staff provide a grant-funding plan to the Advisory Council.
- The Advisory Council also considers NIDDK's goals and needs and advises the NIDDK Director.
- The NIDDK director makes the final funding decisions based on staff and Advisory Council advice.

Post-Review

- **Not Funded – What Next?**
  The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, NIH has resources available to help applicants prepare a possible resubmission. Applications in response to a specific initiative with set-aside money typically cannot be resubmitted, but the Program Official should be consulted about next steps.

- **Fundable Score – What Next?**
  If an application results in an award, the applicant will be working closely with the NIDDK Program Official on scientific and programmatic matters and a Grants Management Officer on budgetary or administrative issues.

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

> ***The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.***

How do I get started?

You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:** https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement
4 Extension
5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution
8 Change of Institute or Division (noncompeting continuation)
9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR*, *NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available. Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Teresa Lindquist, lindquit@niddk.nih.gov or 301-451-6418.

Grant Review-Related Policies

Foreign Organizations

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a significant foreign component.

Research Involving Human Subjects

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its scientific review groups (SRGs) and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations (Code of Federal Regulations, Title 45 Part 46).

There are several considerations for review of applications involving human subjects. These can be clustered into two broad areas: Protection of subjects from research risks; and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

SRGs assign inclusion codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below). The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections (OHRP) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL: http://grants.nih.gov/grants/peer/hs_review_inst.pdf.

Definitions:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. A subset of research involving human subjects

may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

Clinical research is defined as: (1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. (Excluded from the definition of patient-oriented research are in vitro studies that utilize human tissues that cannot be linked to a living individual.) Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; or (3) Outcomes research and health services research.

A Clinical Trial is operationally defined as a prospective biomedical or behavioral study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions.

An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

A ***valid analysis*** is required in phase III clinical trials. This means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis are:

- Allocation of study participants of both sexes/genders and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Research Conducted in a Foreign Country: For foreign awards, and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Children: For purposes of this policy, a child is an individual under the age of 21 years. This definition does not affect the human subject protection regulations for research on children (45 CFR 46) and their provisions for assent, permission, and consent, which remain unchanged. State laws define what constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

Exemption from Human Subjects Regulations

If the applicant designates an exemption from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, although reviewers need not evaluate questions related to research risks or the inclusion of women and minorities, the appropriate inclusion of children ***DOES*** need to be addressed for these applications.

Protection of Human Subjects

If the proposed research involves human subjects, and does not qualify as being exempt, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

- ***Risks to the subjects***
- ***Adequacy of protection against risks***
- ***Potential benefit of the proposed research to the subjects and others***.

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Women and Minorities in Study Populations

There are clear scientific and public health reasons for including women and minorities in study populations. Accordingly, the NIH requires that applications for clinical research give appropriate attention to including members of these groups in studies. If this is impossible (for example, because the disease occurs only in men or is prevalent only in one racial or ethnic group), or is inappropriate with respect to the health of the subjects, a strong scientific rationale or other well-supported justification is necessary. Unless the rationale/justification is compelling, NIH will not fund such applications. This policy covers research grants, cooperative agreements, and research contracts.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These inclusion codes, described below, appear on the summary statement.

Council will consider the degree to which the applicants have addressed this policy when it evaluates applications. Applications with inadequate representation of women and minorities and/or inadequate justification may be deferred, approved based on portfolio considerations, or approved with the condition that staff will ensure compliance with the policy before award. Council will be subsequently notified of awards for these types of approvals.

The NIH will not award research grants, cooperative agreements, or contracts to applicants who do not follow this policy.

Inclusion of Children as Participants in Research

To ensure that adequate data is developed to support the treatment of modalities for disorders and conditions that affect children, as well as adults, it is the policy of NIH that children (i.e., individuals 21 years of age and under) must be included in all human subjects research conducted or supported by

the NIH. Children will not be excluded from this policy unless there are scientific and ethical reasons not to include them in the research being conducted; well-supported justification for the exclusion will be necessary. This policy applies to all research involving human subjects, **including** research that is otherwise "exempt". Proposals for research involving human subjects **must** include a description of plans for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion.

The section in the application titled "Inclusion of Children" should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan **must** also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Specific exclusionary circumstances and other pertinent information on the inclusion of children in NIH-supported research may be found at: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Use of Human Embryonic Stem Cells In NIH-Supported Research

The National Institutes of Health (NIH) has published final "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines).

On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.* The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.

These Guidelines implement Executive Order 13505, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH policies and procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH stem cell research.

EFFECTIVE DATE: These Guidelines are effective on July 7, 2009.

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On April 23, 2009 the NIH published draft Guidelines for research involving hESCs in the Federal Register for public comment, 74 Fed. Reg. 18578 (April 23, 2009). The comment period ended on May 26, 2009.

The NIH received approximately 49,000 comments from patient advocacy groups, scientists and scientific societies, academic institutions, medical organizations, religious organizations, and private citizens. The NIH also received comments from members of Congress. Read the NIH response to the public comments that addressed provisions of the Guidelines at http://stemcells.nih.gov/policy/Pages/Default.aspx

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NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR RESEARCH USING HUMAN STEM CELLS

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human embryonic stem cells (hESCs) and certain uses of induced pluripotent stem cells (See Section IV). The Guidelines implement Executive Order 13505.

Long-standing HHS regulations for Protection of Human Subjects, 45 C.F.R. 46, Subpart A establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. *When research* involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 C.F.R. 46, Subpart A. Applicants should consult http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

It is also important to note that the HHS regulation, *Protection of Human Subjects*, 45 C.F.R. Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 C.F.R. § 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidances at http://www.hhs.gov/ohrp/policy/index.html#topics

To ensure that the greatest number of responsibly derived hESCs are eligible for research using NIH funding, these Guidelines are divided into several sections, which apply specifically to embryos donated in the U.S. and foreign countries, both before and on or after the effective date of these Guidelines. Section II (A) and (B) describe the conditions and review processes for determining hESC eligibility for NIH funds. Further information on these review processes may be found at www.NIH.gov. Sections IV and V describe research that is not eligible for NIH funding.

These guidelines are based on the following principles:

1. Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
2. Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

As directed by Executive Order 13505, the NIH shall review and update these Guidelines periodically, as appropriate.

II. Eligibility of Human Embryonic Stem Cells for Research with NIH Funding

For the purpose of these Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and

tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. All of the processes and procedures for review of the eligibility of hESCs will be centralized at the NIH according to the guidelines available at http://stemcells.nih.gov/policy/Pages/Default.aspx.

III. **Use of NIH Funds**

Prior to the use of NIH funds, funding recipients should provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs are listed on the NIH registry.

IV. **Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding**

This section governs research using hESCs and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

V. **Other Research Not Eligible for NIH Funding**

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09), otherwise known as the Dickey Amendment.
B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, scientific review groups, and Advisory Councils to share this responsibility and review research activities for compliance with the Public Health Service policy for the care and use of vertebrate animals. The general intent of the law and policy can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists;
- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain, or injury. Special attention

must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Any comments or concerns that scientific review group members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; a "comment" is a scientific review group observation that will be communicated in the summary statement as a suggestion to the principal investigator. For projects involving animals, the species used is separately identified at the end of the "Description" in the summary statement. Any comments or concerns that members have regarding treatment and welfare of research animals used in the project are explained in a separate paragraph in the summary statement. Any questions Council members may have should be directed to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) staff.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below).

No research involving animals may be conducted or supported by NIH until the institution proposing the research has provided a written assurance acceptable to NIH.

Inclusion Codes

Gender, Minority, and Children Codes

An NIH-Defined CLINICAL TRIAL? Y Or N

GENDER CODE	**MINORITY CODE**	**CHILDREN CODE**:
First character = G	*First character* = M	*First character* = C
Second character: 1 = Both Genders	*Second character*: 1 = Minority & Non-minority	*Second character*: 1 = Both children & adults
2 = Only Women	2 = Only Minority	2 = Only children
3 = Only Men	3 = Only Non-minority	3 = No children included
4 = Gender Unknown	4 = Minority Representation Unknown	4 = Representation of children unknown
Third character: A = Scientifically Acceptable U = Scientifically Unacceptable	*Third character*: A = Scientifically Acceptable U = Scientifically Unacceptable	*Third character*: A = Scientifically Acceptable U = Scientifically Unacceptable

Vertebrate Animal Codes

Code 10 No Live Vertebrate Animals Involved

Code 30 Live Vertebrate Animals Involved, no SRG Comments or Concerns

Code 44 Animals Involved - Certified - SRG Concerns
Code 45 Animals Involved - No Assurance - No SRG Comments or Concerns
Code 47 Animals Involved - No Assurance, SRG Comments
Code 49 Animals Involved - No Assurance, SRG Concerns

Biomedical Safety

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the scientific review group in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement.

In the case of research involving human immunodeficiency virus, researchers are expected to follow the latest Centers for Disease Control and Prevention recommendations and guidelines for health care workers and laboratory personnel. In research involving recombinant DNA, assessment of an applicant's compliance with Public Health Service guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

Advisory Council Policy/Logistical Documents

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of Council must return the material given to them to the Executive Secretary at the conclusion of the meeting. All materials members have received at home or at their institutions also must be returned for disposition.

There should be no direct communication between members of Council and applicants. In addition to legal considerations, pre-mature notification of recommendations to applicants often leads to misinterpretation and distortion of discussions and recommendations.

As soon after the Council meeting as possible, applicants will be notified by NIDDK staff about the status of their applications.

Conflict of Interest

NIH takes extreme precautions to avoid placing Council members in situations where there might be an actual or apparent conflict of interest. Thus, at each Council meeting, procedures are delineated to avoid such conflicts.

A member must be absent from the meeting room during review of an application submitted by an institution, or a component of a system of institutions, in which the member or member's spouse, parent, child, partner, or close professional associate is an employee, or in which there is a directive or consultative relationship or financial interest. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

The NIH has been granted a regulatory waiver by the Office of Government Ethics so that faculty of multi-campus institutions of higher education who serve as experts or consultants to DHHS may participate in matters affecting one campus of a state multi-campus institution if the expert's disqualifying financial interest is employment with no multi-campus responsibilities at a separate campus.

Additionally, a Council member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, a recent collaborator, or a close personal friend. Further, a member should not take part in the discussion of an application from a scientist with whom the member has had long-standing differences which reasonably could be viewed as affecting the member's objectivity.

Council members present at each Council meeting sign a statement certifying that they did not participate in the discussion of, or vote on, any application from their own institution or an institution in which they have a financial interest.

Though the staff attempts to identify possible conflicts of interest and bring them to the attention of the Chairperson, the National Diabetes and Digestive and Kidney Diseases Advisory Council needs the assistance of members to ensure that such conflicts do not arise.

Lobbying

Technically, Council members are Government employees and governed by DHHS standards of conduct during the days they are being paid for duty. Thus, during the full midnight-to-midnight period of each of these days, members cannot transact personal business, enter into personal activities with the Legislative or Executive branches of Government, or discuss with NIH staff matters pertaining to their institution's federally funded activities. During this same period, members of Council also must not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Freedom of Information and Privacy Act

The Freedom of Information Act (FOIA) of 1967 and the Privacy Act of 1974 have significantly affected the NIH review and disclosure processes. Under FOIA, a person may obtain access to any Government record, including records about himself or herself, unless the records fall within one of nine exemptions to the Act. The Privacy Act, on the other hand, is limited to records about individuals which are maintained in a "system of records" from which information is retrieved by his or her name or other personal identifier.

For example, under FOIA, third parties may receive copies of awarded grant applications, but they may not received copies of applications that were scored but not funded or applications that were not recommended for further consideration. Also, under the Privacy Act, Principal Investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports and summary statements, but not individual reviews. Reviewers' written comments are not retained after their substance has been incorporated into summary statements or site visit reports.

The Freedom of Information and Privacy Acts

	FREEDOM OF INFORMATION REFORM ACT OF 1986 (P.L. 93-570)	**PRIVACY ACT OF 1974 (P.L. 93-579, DEC. 1974)**
PURPOSE	To allow access by the public to government records.	To provide safeguards for an individual against invasion of personal privacy.
SCOPE	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • methods whereby public may obtain records; • types of records available to the public; • exemptions that permit agencies to withhold certain types of records	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to*:* • any system of records from which information is retrieved by an individual's name, identifying number, or other identifying particular assigned to an individual; • any system of records maintained by a government contractor if the agency provides by contract for the "operation by or on behalf of the agency to accomplish an agency function."
REQUIREMENTS	Requires Federal agencies to: • publish in the Federal Register organizational descriptions and locations of agency records; • make all Agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying; • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting records; • make records promptly available to any person following the established guidelines for requesting such records; • make available for public inspection a record of the final votes of each member in every Agency proceeding, except as exempted; • release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletions of commercial information, information that would invade personal privacy, and internal government options and advice.	Requires Federal agencies to: • permit individuals to determine what records pertaining to them the agency collects, maintains, uses, or disseminates; • permit individuals to prevent records pertaining to them obtained for a particular purpose from being used or made available for another purpose without their consent; • permit individuals to gain access to information pertaining to them in agency records, to have a copy made of their records, and to correct or amend their records; • collect, maintain, use, or disseminate records of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of information; • be subject to civil or criminal sanctions as a result of willful or intentional actions which violate any individual's rights under the Act; • publish annually a notice in the Federal Register indicating the existence and character of the system records..
SUMMARY	Makes possible disclosure of policy, procedures, and records to the public.	Safeguards the privacy of individuals in the face of disclosure.

Travel Procedures for NIDDK Advisory Council Members

When you travel to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meeting, **you are considered a Government employee** of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and therefore traveling on official Government business. Your expenses are reimbursed according to Federal travel regulations.

In order for you to be reimbursed in a timely manner and to ensure that you will be reimbursed for your travel expenses, please be sure to read the information below.

Note: If you will **not be attending** the meeting, please call Dr. Brent Stanfield at (301) 594-8843 to inform him of your absence.

Overview of Expenses and Reimbursement

Allowable consultant expenses for members of NDDKAC are as follows:
Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is $0.565 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently $71.00 per day for the Washington, D.C., metropolitan area. You will receive ¾ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. You will receive a $200.00 honorarium for each day or fraction of a day that you attend the Advisory Council meeting. These checks are processed separately using Electronic Funds Transfer.

Travel Instructions

NIDDK will fax an NIH travel order to you prior to your travel.

Per Federal travel regulations, all Government employees are required to use their agency's travel management center. Therefore, **you are required to book your air or train fare through Omega World Travel (OWT) and you must book coach class.** Please mention you are attending the "NIDDK Advisory Council Meeting on_____(date)_____in Bethesda, Maryland.

It is the Council member's responsibility to contact Omega Travel at 866-264-8281 (for after-hours emergencies please contact 800-285-6342) to confirm/change the travel reservation. OWT's local number is 301-984-8985' fax is 301-984-9552. .All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

What do I need to do to make a change on my airfare so I can be reimbursed for additional expenses due to changes?

If you need to make a change on your airfare, you are required to contact OWT (see phone number s above). **We recommend that you carry their after hours number with you in case you need to make a change to your airfare or train ticket.**

What if I don't contact OWT? How will this affect my reimbursement?

Please note that if you book either business class for airfare and/or a train ticket, you will not be reimbursed. In addition**, you can not pay the difference for a change in your airfare or train ticket by paying the additional money in cash.** Again, you must contact OWT; they will charge additional travel expenses to our government account. *Travelers who choose to not use Omega World Travel to make their travel reservations will not be reimbursed by NIH/NIDDK*.

Will I receive a confirmation from OWT of my airfare or train ticket reservations?

Yes. OWT will process your reservation with an electronic ticket and send you a confirmation notice via email. Retain this confirmation number. To view your reservation online go to www.viewtrip.com.

Can I be reimbursed for rental car expenses?

Rental car expenses are rarely approved and must be pre-approved on the travel order. Under no circumstances will rental care expenses be reimbursed without prior authorization.

Can I be reimbursed for the expense of using a sedan instead of a taxi

You can always be reimbursed for taxis but not for use of a sedan.

What documents should I carry with me when I travel?

- OWT's phone numbers in case you need to make a change in your itinerary

OMEGA WORLD TRAVEL After hour's emergency: (800) 285-6342 Outside the local area: (866) 264-8281 Local Area: (301) 984-8985 Fax: (301) 984-9552

- A **government-issued photo ID** (license, passport, etc.)
- A **copy of your electronic ticket** with confirmation number.
- The **NIH travel order** to verify that you are traveling on official Government business. NIDDK will fax the travel order to you prior to your travel.

Hotel Information

NIH/NIDDK books and pays for hotel rooms for all Council members. Hotel room confirmation numbers will be submitted to you prior to your departure. Also please confirm your check-in and check-out dates, especially if arriving late. You will be lodging at the American Inn of Bethesda.

American Inn of Bethesda
8130 Wisconsin Avenue
Bethesda, MD 20814
T: (866) 785-1812 or (301) 656-9300
F: (301) 656-2907
http://American-Inn.com

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include:

- Travel stubs or the travel itinerary showing the price of the ticket
- Other travel related receipts over $75.00 (e.g., receipts for taxi fares, tolls, parking fees)
- Original hotel bill
- Rental car receipt (reimbursement must be pre-approved).

Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days. No receipts are needed. (See M&IE above.)

Travel Expense forms and receipts should be sent within 5 days of your complete travel to:

Dora A. Abankwah, Assistant to Director
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 713A
6707 Democracy Boulevard
Bethesda, MD 20892-5452

Once your completed Travel Expense Form with all receipts attached is received, you will be sent a travel voucher for your signature. The travel voucher is a document prepared at the conclusion of your trip itemizing all claims for reimbursement.

After the travel voucher is received at NIH, the payment will be deposited into your banking account within 14 business days in the amount indicated on the travel voucher as "NET TO TRAVELER."

Note: Your honorarium will be processed separately as noted above.

If you have any questions, please do not hesitate to contact Dora at 301-594-8843 or email her at abankwahd@niddk.nih.gov.

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

(FEBRUARY 13-14, 2013 Council Meeting)

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket $_____
- **Original Hotel** itemized receipt:
  - Room Rate $_____
  - Hotel Taxes $_____
  - Phone Calls ($5.00 per day are reimbursable) $_____
- Other travel-related receipts **over $75.00** $_____
- Rental car (reimbursement must be pre-approved) $_____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x $0.565 cents)
  $_____
- Parking Fees $_____
- Taxis:
  - From Residence to Terminal $_____
  - From Terminal to Hotel $_____
  - From NIH Campus to Terminal $_____
  - From Terminal to Residence $_____
  - Other $_____
- Tolls $_____
- Other miscellaneous expenses $_____

  (Please describe:_____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of $71.00per day while you are on official government business. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

SIGNATURE: _____

DATE: _____

NIDDK Advisory Council Orientation Reference Links
February 2013

General Background Information About the Council

- **Advisory Council Home Page on the Web**: http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/
- **Advisory Council Charter**: http://www2.niddk.nih.gov/NR/rdonlyres/A95572B6-D3F2-4199-8900-1AFB7DA5EE19/20236/2012NIDDKChartersigned.pdf
- **Advisory Council Membership Roster**: http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/AdvisoryCouncilRoster.htm

  Advisory Council Operating Procedures: http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/AdvisoryCouncil/AdvisoryCouncilOperatingProcedures

General Background Information About NIDDK and Funding Policies

- **NIDDK Mission**: http://www.nih.gov/about/almanac/organization/NIDDK.htm
- **NIDDK Organization**: http://www2.niddk.nih.gov/AboutNIDDK/Organization/default.htm
- **NIDDK Funding Policy:** http://www2.niddk.nih.gov/Funding/Grants/FundingPolicy.htm

Administrative Matters Regarding Council Membership

- **Confidentiality and Conflict of Interest:**
  - **Confidentiality**: http://www2.niddk.nih.gov/NR/rdonlyres/0779AF27-CAF7-4D91-9D73-6246B26B50D4/0/AI12.pdf
  - **Conflict of Interest**: http://www2.niddk.nih.gov/NR/rdonlyres/670481DD-2214-411B-8AC3-380F17C5EB80/0/AI1.pdf
  - For Grantee Financial Conflict of Interest see http://grants.nih.gov/grants/policy/coi
- **Lobbying:** http://ethics.od.nih.gov/topics/lobbying.htm and http://ofacp.od.nih.gov/policies/pdfs/BanonLobbyistsOFACPPolicy_Final.pdf
- **Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book:** http://www2.niddk.nih.gov/AboutNIDDK/Organization/Divisions/DEA/ReviewBranch/DEAReviewBranchBook
- **Travel Reimbursement:** (see Travel Expenses and Reimbursement and Sample Expense Form, in Advisory Council Policy/Logistical Documents)

The Grant Process

- **NIH Dual Levels of Review:** http://www2.niddk.nih.gov/NR/rdonlyres/C2317A28-B024-4864-82C9-EAF83BCBBA55/0/dual_rev_system.pdf
- **NIH Funding Instruments:** http://www2.niddk.nih.gov/NR/rdonlyres/D67EEF97-C25F-4CB9-AA5F-1A039A009DDB/0/fund_instr.pdf
- **Review Process from Application to Award:** http://www2.niddk.nih.gov/NR/rdonlyres/965D13B7-5E71-4051-9D9F-C497C931F5A5/0/rev_pro_app_award.pdf
- **Peer Review Process Video:** http://public.csr.nih.gov/Pages/default.aspx
- **Peer Review Guidelines and Information:** http://public.csr.nih.gov/ReviewerResources/Pages/default.aspx
- **Grant Policies and Regulations**
- **Freedom of Information Act & Privacy Act:** http://www2.niddk.nih.gov/NR/rdonlyres/E4CC0173-DBA2-4C4F-9A19-9202A5725173/0/AI10.pdf and http://www2.niddk.nih.gov/NR/rdonlyres/81998744-5A0D-43D1-BE25-ABE9C0C79823/0/AI102.pdf

Recent (last 12 months) Notices on Policy, etc.

NOT-OD-12-027 Notice of NIH's Creation of the National Center for Advancing Translational Sciences and Anticipated Implementation Plan

NOT-OD-12-035 Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts

NOT-OD-12-041 New NIH policy on Efficient Spending Related to Grants Supporting Conferences and Meetings

NOT-OD-12-043 New Electronic Submission Process Now Available for Administrative Supplement Requests

NOT-OD-12-108 The Division of Receipt and Referral will use eRA Commons to Communicate with Applicants and Applicant Organizations

NOT-OD-12-128 Time Limit on NIH Resubmission Applications

NOT-OD-12-129 Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval

NOT-OD-130 Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards)

NOT-OD-139 Notice of Changes to Policies and Procedures for FY2013 NIH Awards to Foreign Institutions

NOT-OD-12-140 Notice of NIH Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support

NOT-OD-12-143 NIH Announces One-time Financial Conflict of Interest (FCOI) Reporting guidance for Certain Fiscal Year 2012 Awards Issued On Or After August 24, 2012

NOT-OD-12-157 Publication of the Revised NIH Grants Policy Statement (Rev. 10/1/2012): Policy Changes and Clarifications Notice

NOT-OD-12-141 Interim Guidance for Videos Submitted as NIH Application Materials

NOT- OD-12-159 Proactive Compliance Oversight Program-Financial Conflict of Interest Requirements for NIH-Supported Institutions

NOT-OD-12-161 NIH Announces Plans to Transition to Electronic Submission of Multi-Project Applications

NOT-OD-12-160 Upcoming Changes to Public Access Policy Reporting Requirements and Related NIH Efforts to Enhance Compliance

NOT-OD-13-010 Advance Notice: Revised Policy for Managing Conflict of Interest in the Initial Peer Review of NIH Grant and Cooperative Agreement Applications